UNITED STATES OF AMERICA

DEPARTMENT OF DEFENSE

ARMED FORCES EPIDEMIOLOGICAL BOARD

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MEETING

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TUESDAY,

SEPTEMBER 12, 2000

The Board met at 7:30 a.m. at the Walter Reed Army Institute of Research, 503 Robert Grant Avenue, Silver Spring, Maryland, at 7:42 a.m., DR. F. MARC LaFORCE, President, presiding.

PRESENT:

Francois M. LaForce, M.D. [President, AFEB]
Linda L. Alexander, Ph.D.
David Atkins, M.D.
S. William Berg, II, M.D., M.P.H.
COL Dana Bradshaw, USAF, MC
COL Crumrine
Pierce Gardner, M.D.
L. Julian Haywood, M.D.
Dr. Charlie Hoke
Philip J. Landrigan, M.D., M.Sc.
CDR Sharon Ludwig
LTC Vic MacIntosh
Stanley I. Music, M.D., D.T.P.H.
LTC Neville
Stephen M. Ostroff, M.D., M.P.H.
LTC Rick Riddle, Acting
Dr. Paul Smith
Rosemary K. Sokas, M.D.
CAPT Kenneth Schor, MC, USN
COL Ben Withers, MC, USA
COL Benedict Diniega, MC, USA
AFEB Executive Secretary

I-N-D-E-X

I-N-D-E-X (Continued)

P-R-O-C-E-E-D-I-N-G-S

(7:42 a.m.)

WELCOME

PRESIDING OFFICER LaFORCE: First off, this is my first visit to this facility, which apparently just opened. When did it open, March or something? Was it last March?

MR. MILLER: We've been moving in since May of last year.

PRESIDING OFFICER LaFORCE: Since May of last year. What a spectacular place. I'm looking forward if we have a chance to wander around a little bit later on, but what a beautiful facility. So it's obviously a pleasure for the Board to meet here.

Other than saying hello, I'm going to turn this over to Ben in terms of some administrative details for right now. Ben?

ADMINISTRATIVE REMARKS

COL DINIEGA: Good morning and welcome to the fall meeting. First off, I want to thank WRAIR and Colonel Crumrine for hosting the meeting. We missed one last year, primarily because they were in the process of moving. So there was an agreement between he and I to hold it off until

they reopened and settled back in. They're settled in, and they're very willing to host us.

There's been a long relationship between the AFEB and WRAIR and especially the Division of Preventive Medicine. I also want to thank the Division of Preventive Medicine for their assistance in the pre-preparations, especially Mr. Steve Gubenia.

We are in a transition phase at the AFEB. So our membership with the people rotating off this past summer is down to 13. And ten of the members said that they'd be here today. We'll go around sometime later on and have them introduce themselves.

I also want to mention that we have several preventive medicine liaison officers that have rotated. And at least one I recognize in this forum. First is Captain Dave Trump, who has left his position at Health Affairs. Captain Trump is there. And he is now at the Uniformed Services University under a different kind of pressure.

Lieutenant Colonel Frank Souter is a Canadian medical liaison officer, has retired, and is replaced by Lieutenant Colonel Fensome, who, unfortunately, couldn't be here today.

And then for the Coast Guard, Commander Tedesco has turned over the reins of liaison officer to the Board to Commander Sharon Ludwig, who is the preventive medicine officer. One of them was supposed to be here today. I'm sure they'll show up later.

We have an NCO provided by WRAIR to help us with the administrative things during the meeting. That's Staff Sergeant Truss, and she is standing here in the back. So if you need any help of any sort, messages, telephone calls, taxies, et cetera, directions, Sergeant Truss will be more than willing to help you.

The bathrooms are outside and to the right, catty-corner right here in the hallway. There is a cafeteria if you go straight down the hallway through the double doors to the left. And they have more substantial things than the coffee that I have here. For the coffee, we're asking for donations, 25 cents a cup or a dollar for the whole day, with whatever you want to do.

Thanks to Jean Ward for her administrative support in preparing for the meeting. She's unable to go to the meetings anymore, mainly because she has a medical profile

which limits her to no more than an R standing, an RFP.

As I said, we're in an in-between phase. The preventive medicine staff officers met and reviewed the CVs that were submitted as nominations to the Board and actually selected seven people, but we ran out of people for one of the positions. And so six people are in the appointment process. I'll be soliciting on a continuous basis any recommendations for people to sit on the Board in any of those three committees.

I expect those appointments to be ready for their meeting, the winter meeting, which will happen January-February time frame, probably February time frame, of 2001.

There are sign-in sheets on the outside. If you haven't signed in, please sign in sometime during the break or during the morning if you missed it on the way in.

As I mentioned, there's coffee only available in the room. Please be careful of the cups and don't ruin Colonel Crumrine's beautiful executive board room.

The cafeteria for lunch, also options for lunch are the PX complex north of the building

has a snack bar to include a deli section. And then across the street on Brookville Road, there are a couple of eateries, a deli, and a Mexican restaurant. So we'll have lunch, enough time to give people if people want to go elsewhere to do that, about an hour and 15 minutes.

Telephones for messages incoming go to the commander's office. The number is (301) 319-9100 or 9209; the fax machine, (301) 319-9227. And if anybody needs a taxi at any time during the meeting, Barwood Taxi is at (301) 984-1900.

A reminder to the Board members, the travel settlements at the end of this meeting, after you get home, if you can fill them in, the 1352s, and send them in to Jean. And we'll review them and send them in for payment. And then once you get your white paid settlement voucher, be sure to send Jean a copy so we can track our expenses and our budget.

In the past, there have been some travel glitches where members have had to make last minute changes. If you'd take a look for those who flew in the itinerary from Carlton, on the last page is an 800 number that you can call 24 hours a day that Carlton has set up.

You can always work through them to make travel changes. And that would be whatever you made with them originally, usually the rental car and the airline. But you can do that at any time if you need to make travel changes.

We sent out a letter to the Board members with calendar. We need your non-available dates so we can look at the meetings for next year. We want to stay in probably the February time frame for the winter meeting in a nice warm place. And the Air Force is hosting next time. I mentioned Hickam, anyway someplace warm, no bias.

And then the meeting after that is our annual BW threat review, and that's normally in the May time frame. The chairman releases by the books they're supposed to review and releases a new BW threat list by 1 April. That has varied from year to year to mid April to end of April to sometime in May and one year none at all as they felt that they didn't need any change.

It's a responsibility of the Board to review those BW threats and make appropriate countermeasure recommendations. So I think the best timing for the meeting is mid May for that meeting. And that will be somewhere in the D.C.

area.

And then the fall meeting, I think September is a very good time frame for the meeting, for most of the people involved with the meeting. So we do need the calendars back as soon as possible.

The agenda if you take a look at the agenda, it's pretty full. For the most part, speakers have 20 minutes and 10 minutes for discussion. Please leave time for the discussion period because that's what most people want to see from the Board, what comments they have on what's being presented.

Because this is a down time, I've tried to limit the amount of formal questions to the Board. With only 10 people, subcommittees will be comprised of anywhere from 2 to 3 people.

But there are two questions. One is the ongoing ergonomics question, and there will be an update by Lieutenant Colonel Lopez this afternoon.

The other question is a more formal question, and that's from the U.S. Navy. And that's looking at a criteria for assessing the performance of microbial-based cleaners. And we'll hear that presentation this afternoon, but this is

an area where in my discussions with people there is no regulation on those products. And so as the services start buying them, they want to take a look at what their performance criteria should be that they should be asking for.

I had sent that out on e-mail as a read-ahead. I think I only got one person who couldn't open the attachment this time. There have been problems with things going out in Word and people unable to open the attachment. If you let me know in the future, what I'll end up doing is just copying the attachment right into the body of the text of the e-mail.

Tomorrow morning there are two very, very -- they're all interesting presentations but two very interesting presentations with a historical slant.

If you look at your agenda, we need to make a correction. I have down there the "Disease and Non-battle Injuries" at 8:15 tomorrow morning "During the Korean War," Mr. Smith. It should be Dr. Smith. Dr. Bill Smith is the Chair of the Military History Department at USU. He was an understudy to Dr. Joy for many, many years. When Dr. Joy stepped down, he took over the department.

So he'll be giving a very interesting talk.

Also, a long-time previous member and president of the Board, Dr. Ted Woodward has agreed to come and meet the current Board members and also give his comments and viewpoint on the AFEB. And that will be tomorrow morning after Dr. Smith's presentation.

If you take a look at the agenda on the front page, a couple of more corrections. The Health Affairs representative, since Dr. Trump left his position, his position remains unfilled And Lieutenant Colonel Rick Riddle is the acting liaison officer to the Board and is there temporarily. They're working hard to get a replacement. We'll see how that turns out.

Let's see. There was one more. In the 2:15, 1415, presentation block that says, "To be determined," if you want to add "Microbial-Based Cleaners," that's when the question will be raised to the Board. Captain Bohnker, B-O-H-N-K-E-R, -- I think I'm saying his name correctly -- will be making that presentation.

We will have a break midmorning and mid-afternoon also. Did you want to mention the evening activities at this time?

PRESIDING OFFICER LaFORCE: Yes. As many of you know, I'm sort of a bachelor for a while in Georgetown since, unfortunately, we have not sold our house in Rochester yet. So I am a split family. My wife is in Rochester, and I am in Georgetown. We're actually going to move this weekend, but I have the townhouse this week while the AFEB is meeting. And so it's my pleasure to host a reception this evening at 1406 27th Street.

We'll put it down. It's actually very easy to get to from the Dupont Circle Metro stop or the Foggy Bottom Metro stop, either way. And I was hoping that at the end of today's session to invite you all to come by and have some wine, beer, cheese, whatever, at the townhouse.

And then there is a whole selection of restaurants around, those of you who are familiar with east Georgetown. The Ethiopian restaurant is not far down the street. There are Italian restaurants, Vietnamese restaurants all over the place. And then we could split up in various culinary groups and go on from there.

Then it's pretty easy to get back up because the subway, as I say, is right at Dupont Circle or at Georgetown, which then connects to the

line that comes right up here. It's really quite easy.

So I'll have a sort of rough map for this afternoon, but it's really quite simple to get to. Hopefully we'll see many of you this evening.

COL DINIEGA: Just a few more reminders, first to the speakers. Please stay within your allotted time. I'll wave my hand when you're at five minutes if I remember to.

The meeting is being recorded. It's being transcribed. So if you can state your name before you speak or make comments? The only way it can be picked up is through the microphones up here and the table. So if you want to come up, we'll slide the microphone down to anybody who wants to make comments from the audience.

Handouts from the speakers. If you give them to me before your presentation, I'll take care. I will take care of handing it out, and the order of handing it out is first to the table and then, secondly, to the audiences. We will put any leftovers over there on that table.

Then a reminder that this is an open meeting. Anybody can come to the meeting. And there may be members of the media present in the

audience.

With that, we can start.

PRESIDING OFFICER LaFORCE: Okay. It begins with Colonel Crumrine, Commander at Walter Reed Army Institute of Research. Colonel Crumrine?

WELCOME/WRAIR BRIEF

COL CRUMRINE: Good morning. Well, I see familiar faces and unfamiliar faces. I'd like to welcome you all to the combined facility here. It's not only the WRAIR, the Walter Reed Army Institute of Research, but it's the home of the Naval Medical Research Center as well.

As part of a base realignment and closure action in the year of 1995, they have been collocated with us here. So you will see people in the Navy whites and khakis along with the folks in the Army greens. And we do have an Air Force officer up on the third floor now and then as well. So we're pretty much a tri-service organization.

This institution has long been known in the field of preventive medicine and infectious disease. We also have responsibilities in combat casualty care as well and things we call operational medicine. And that research area focuses on sleep and performance issues.

For those of you that have time, I welcome you to wander the facility at your own risk. Ask the researchers what they're doing. You may stay there longer than you expect. They all like to talk about their work. They're, quite rightly, proud of the work they do here.

We also have across the street from this facility this way a pilot bioproduction facility where we can make our own GMP lots of vaccine on a pilot basis and use that as a basic scale-up capability prior to going back out to commercial entities for full-scale production.

So we encompass a lot of work from basic to applied research clear up through to production, small-scale production, of vaccines. And we have the capability for doing clinical trials as well as a sleep suite, which is directly above us, where we can do some of our sleep and performance studies.

With that said, I don't want to take up too much of your time. As I told Ben earlier, I just came back from leave. My "In" box looks like your stack of handouts here.

So if you'll excuse me, after I welcome you, I will bid you a good meeting, welcome. If you're available at lunchtime, I will be glad to

conduct some informal touring for small groups. And I can probably catch a few other guides. If you have specific questions, specific interests, let us know. If there is anything we can do to help you in addition, let us know.

Thank you.

PRESIDING OFFICER LaFORCE: Thank you very much, Colonel.

Let's begin. We're a few minutes early, which is great. The Health Affairs representative, Lieutenant Colonel Rick Riddle?

PREVENTIVE MEDICINE OFFICER UPDATES

LTC RIDDLE: First, good morning. It's a pleasure for me to be here to represent Health Affairs. I can hardly take Captain Trump's place but maybe can fill in in the interim until we have a preventive medicine officer at Health Affairs.

I just wanted to update on a couple of things. As you may know, Dr. Clinton has been appointed as the Acting ASDHA. Dr. Clinton comes to us from the Public Health Service. He's a physician with an M.Ph. So I think he relates very well to the work of the Armed Forces Epidemiological Board.

Dr. Bailey moved over to the National

Transportation Safety Agency. You may have recently seen her on TV addressing the Firestone tire issue. So it's kind of like out of the frying pan into the fire. So she's certainly been busy there.

I did want to thank the AFEB. Recently they did an evaluation of a manuscript for us on the squalene antibodies by Asa, *et al*. We certainly appreciate that, and I think that goes to the merit of the AFEB on our previous responses to Congress on this issue.

They usually had a letter back to us before they received our letter. I think they took the AFEB review with the merit that it deserves. And we haven't heard anything back. So hopefully that reinforced I think the findings that the AFEB had and certainly our feelings with that work and certainly appreciate that from our perspective.

Some of the recent activities at Health Affairs certainly have been focused on the budget, the expansion of care to our beneficiaries under the Warner Amendment. We expect that to come out in the authorization bill, maybe as early as this week. So that's going to be important for us to work through.

Certainly another issue of concern that has been on the table for us is the Boxer amendment in the appropriations bill, which has some severe limitations on our ability within the Department to share information and medical records of active duty and beneficiaries outside DOD. So we're certainly working that issue very hard and hope to make some progress with that.

One of the issues on the agenda for the AFEB today is the adenovirus. And I look forward to the presentations by Dr. Gray and others on that. It might be of some merit in the absence of a vaccine for the AFEB to re-look the preventive medicine and public health practices in place at the recruit training centers and maybe update the prior recommendations that we had as to how we can address the morbidity from adenovirus in the interim because certainly the ability to bring a vaccine online or to have a vaccine is many years down the road. In addition to those issues, I think we need to look at what we can do from a preventive medicine perspective.

We have been working very closely with the Joint Preventive Medicine Policy Group addressing the national influenza vaccine shortage.

And Colonel Bradshaw is going to provide an update to the Board on our current plans and where we're going with that issue.

We certainly appreciate our working with CDC on a myriad of issues and kind of look forward to a relationship there and with the Board and hopefully filling Captain Trump's position and getting a preventive medicine officer on staff.

I think that kind of reflects overall the services' shortage of preventive medicine assets. We have tried to address that issue and certainly hope we have more focus within the services to fill those positions and fill the preventive medicine officer slots.

PRESIDING OFFICER LaFORCE: Questions?

Ben, you're on.

COL WITHERS: Thank you.

Good morning, Board members. I'm Colonel Withers, Army representative to the AFEB. Frankly, I'm going to be very brief this morning. Colonel Bradshaw is going to cover flu. That's really all of our big issue right now. And Major Pavlin will cover West Nile virus in great detail, overall program.

Really, the only thing I wanted to

discuss was a little bit of West Nile virus surveillance results at some Army installations. We've actually only had activity -- we've had a little bit of West Nile surveillance activity at two Army installations this year. Really, none of them is that big a deal but just thought I would bring up something interesting.

One is at Fort Hamilton. That's a tiny, little post, 180 acres. I don't know why we still own it, frankly, but it's on the east side of the Verrazano Narrows Bridge. Of course, it's in the hotbed of West Nile virus activity.

There was a dead crow found there back in late August. So that generated a lot of excitement. The city decided to spray in the area. We have had ongoing, meanly weekly, mosquito-trapping surveillance for mosquitos at most of our installations in the East Coast all summer. This sparked enhanced surveillance.

We did, in fact, conduct enhanced surveillance the night before the city sprayed and, lo and behold, found a couple of mosquitos. Actually, three pools if I've got it right or three *Culex pipiens* mosquitos were found in a pool. A pool is a group of 25 mosquitos sorted by species.

They can all come from the same trap, but they take them and divide them into pools.

Anyway, the spring did, in fact, cause a large knockdown in the mosquito population. The very next night, very few mosquitos were found, only about ten percent, and none infected.

So we're simply continuing ongoing mosquito surveillance. And the locals at Fort Hamilton are also redoubling their efforts to knock down the mosquito population through what they can do around the housing area and whatnot.

At West Point, 50 miles north of New York City, we've also had regular non-enhanced surveillance -- that's weekly -- done by the local engineers and whatnot.

No infected mosquitos have been found at West Point. However, three dead birds were found: one in late August, two in early September. They were a house sparrow and two cedar waxwings.

We dispatched a team and conducted enhanced surveillance for a week or two but decided that no particular extra-area spraying or countermeasures were necessary. So we're simply continuing local measures there, surveillance and local measures.

That's all. Are there any questions? Yes, sir?

DR. LANDRIGAN: Colonel, do the local measures include sending troops around every couple or three days to deal with any standing water; for example, setting up the canvas to --

COL WITHERS: Yes. Our local measures have included just good spraying that should be adequate given the installation and, yes, attention to standing water pools to get rid of them and to spray them as needed.

That's actually done -- you mentioned troops. It's done by the facility engineer at Army installations, actually. It wouldn't be a soldier activity, but our civil engineers would do that.

Any others?

PRESIDING OFFICER LaFORCE: Yes. I assume there have been no suspected cases or any disease related to this, has there?

COL WITHERS: Well, not on the Army installation.

PRESIDING OFFICER LaFORCE: Right.

COL WITHERS: Nationwide I think we've had eight or --

PRESIDING OFFICER LaFORCE: No.

Nationwide I understand that.

COL WITHERS: Yes. Eight.

PRESIDING OFFICER LaFORCE: But within the military --

COL WITHERS: Right. That's correct.

PRESIDING OFFICER LaFORCE: Okay. Fine.

COL DINIEGA: Just a comment. Later this afternoon Major Julie Pavlin will be talking about DOD's West Nile fever surveillance program. And she'll have more detail in what the military is doing specifically on installations within the risk areas.

COL WITHERS: Any others?

(No response.)

COL WITHERS: Thank you.

PRESIDING OFFICER LaFORCE: Thank you, Colonel Withers.

Colonel Bradshaw, the Air Force Surgeon General's office.

COL BRADSHAW: As has already been mentioned, I am speaking I guess for the Air Force but also kind of in a joint capacity today as the current Chair of the Joint Preventive Medicine Policy Group.

As many of you are probably aware, the

CDC in July mentioned that there was going to be a delay and essentially a functional shortage of the influenza vaccine this year.

The Joint Preventive Medicine Policy Group working with several others from the logistician community, some of our infectious disease folks, someone from the pharmacoeconomic center, and several other individuals are working on a plan to take the CDC recommendations and try to move forward with them. So this is what we have been working on.

And so I agreed to try and take the overall view of the influenza vaccine shortage approach. And then you may hear some things from some of the other preventive medicine officers on some things pertinent to their particular service, but that's what I will be focusing on.

So if we can go ahead, go to the next slide. As noted, the CDC came out with their first notice on this in July. Where they said there was a definite delay and possible shortage, this was because of lower than expected production yields, but this was mainly with the Panama A strain, which is a new strain added this year.

Some of the companies had some problems

in initially growing this and the eggs. Those problems I think have since been resolved fairly well, but a couple of the manufacturers -- we have four licensed manufacturers here in the United States.

And two of the four had problems in their production line with FDA processes. One of those seems to have solved those, but one of them still is not in production. So that has complicated the problem that we had with growing the new strains that were added.

Next slide. Because of this, CDC decided that since we would have a functional shortage and delay, that for some people, particularly those that organized campaigns would be in place for, that those should be delayed at least until November.

The routine vaccination of individuals who are at high risk for complications of influenza would go ahead and proceed as usual through their health care providers, but any other individuals, those things should be delayed.

In this setting, it was mentioned that we should develop provider-specific contingency plans to deal with the problem: the influenza

vaccine shortage.

Next slide. Now, in the Department of Defense, in the military, we historically have used about 2.8 million doses a year. Now, currently what we have on hand is just barely 240 or 230 thousand doses, which one manufacturer has supplied and got out on time. And we have that in the repository at the Defense Supply Center in Philadelphia.

Our major supplier, one of our contractors, supplies 2.5 million of our 2.8 million doses. Unfortunately, this supplier is one of those that has had problems with their FDA processes. And so they are going to be delayed, but the word is that they expect to have vaccine available early in October. And that is not changed, but still it's a little bit iffy. There are another 40,000 doses that we expect from another manufacturer in October-November time frame.

Next slide. Now, this is some estimates that we did through the Population Health Support Office and PASBO, which is the Army's patient administration information source.

Looking in the SIDR/SADR databases for

our populations over 65, which is one of the high-risk categories, the users, which is sort of a construct, actually, a composite based on calculations of people that use various different services at the facilities, -- so, for instance, a person who uses the pharmacy only, the pharmacy benefit only, would be a .2 FTE, or full-time equivalent. So it's kind of a complex calculation here, but this is just an estimate for us of who actually is using our facilities.

That's about 360,000, which you can see quickly dwarfs the available vaccine that we have on hand if indeed every one of those was really using our facilities in an eligible beneficiary.

For those that are high-risk medically, those with things like diabetes or chronic obstructive pulmonary disease or other problems, those we found looking at the ICD-9 codes, we have about 50,000 of those. So those we probably should not have too much of a problem with.

For our pregnant patients, those in second and third trimester of pregnancy, we have another 50-some odd thousand. So if it was just those two groups, we should probably adequately be able to cover those individuals with the vaccine

that we currently have on hand. So the big question mark is really about the elderly population, how many of those actually would be involved.

If we look at all eligibles, for instance, most of our over 65 are supposed to be taken care of by Medicare. But if all of those hear there's a shortage and flood into our military treatment facilities, then we could, of course, be overwhelmed fairly quickly.

Go ahead. Next slide, please. One of the problems is that the current CDC recommendations did not specifically discuss the military issues, specifically the military issue of readiness.

Now, the pandemic plans that have been discussed in draft form do include infrastructure. And that includes like emergency first responders.

It also specifically mentions military and the military readiness issue, but that's in the pandemic setting. And when I brought this up at the last Advisory Committee for Immunization Practices meeting, this shortage plan really doesn't address or include that.

As a consequence, the Joint Preventive

Medicine Policy Group has tried to look at this, our issues of military readiness, and try and fit it in with our responsibility to our vulnerable populations to see how we can prioritize them and try and cover all of our responsibilities in the military services and also the Coast Guard.

Next slide, please. This is the vaccine prioritization we have come up with. It very closely follows the CDC recommendations. The one exception is at the top. We have tried to identify some mission-essential or mission-critical personnel which would proceed in parallel with our vulnerable populations, although this we're trying to communicate to our line side that this has got to be very granular. And it's got to be down in the few thousands, even at the most tens of thousands, and that it has to be really looked at carefully to see who really is mission-essential.

Of course, the other things follow fairly straight in line except that we shortly after the major, the high-risk people, and the health care workers, we start moving in our other operation of military personnel, other populations where epidemic outbreaks might be a problem, such as our trainee populations, and then on down the

line. This fairly well tracks pretty closely with the CDC recommendations.

Next slide, please.

COL GARDNER: Can you give us some numbers on those seven groups?

COL BRADSHAW: Well, that's what we tried to do with the earlier slide. We mainly looked at the high-risk folks because those are the ones that we knew would be right up front. What we don't have a good handle on is, for instance, what's going to end up being mission-critical.

We have very large lumped categories, for instance, like the folks that are forward in southwest Asia, in Korea, which are hot spots, but among those, for instance, there is also shipboard populations, where we think people would be more vulnerable and they would also be kind of mission-critical. Those could be very large populations indeed. And, again, that would tend to overwhelm our 230,000 doses that we have in hand.

So that's where we're going to have to pare things back with the line and look at: Well, should it be pilots, air traffic controllers, special operations personnel, a few other people in command and control? It really has to be looked at

in specific detail and get very granular.

Next slide, please. This is just looking. Sharon Ludwig took the information that was in the spring MMWR, which were the general recommendations on influenza that CDC put out, looked at the hospitalization rates, took the lowest category as one that did rate ratios.

And this kind of shows you the higher-risk versus lower-risk populations, "higher-risk" meaning those medically high at risk and what their risk for hospitalization is.

And it's a U-shaped curve where the very young and very old are really at most risk. And if you'll notice, those over 65 as a whole category are at higher risk than the next category down who have medical conditions that would give them an indication for vaccine. So this just kind of helps put the prioritization scheme in some perspective.

Next slide, please. We mentioned antiviral drugs in our plan. However, they're really not recommended for widespread use in prophylaxis. Treatment only gains you about an extra day. And there's no good evidence to show that it prevents complications.

So CDC is not really recommending a lot

of use for the antivirals. However, certain populations, like our trainee populations, if we identify an outbreak, we can cohort them. We can put them on antivirals. And that might be a place where we could utilize antivirals.

Next slide. This is the vaccine distribution plan. We currently have about ten percent of the vaccine on hand, as you heard earlier. We plan for the supply center to distribute the vaccine proportionally based on the historic requirements that have been submitted by the military treatment facilities.

Local distribution would then be by the priorities that we have agreed upon or are trying to agree upon. And then the additional vaccine would be distributed when it becomes available. That's our current plan for distribution.

Next slide. This just notes that we have been able to plug in from Captain Trump's previous involvement with the ACIP. I'm taking the interim role in that.

So we are participating in the influenza planning activities. The plan for prioritization is currently being staffed by Health Affairs out through the service SGs and also the Joint Staff

and on the line side.

Next slide. These are just some future recommendations to consider. I think we're kind of caught right now because the majority of our supply is from one of the problem manufacturers. And it may be better that since we have three on contract, maybe we spread that out a little better and it might make us less vulnerable.

We need some surge capacity among the suppliers so that we could shift to another one who is not having production problems. And at the national level, there are questions about: Is there any way to move strain decisions earlier? Of course, we need to look at faster growth methodologies.

Last slide here. I just wanted to quickly mention some responses somebody may have mentioned before, but I know the Board likes to see where we're acting on the recommendations.

The Air Force has implemented varicella screening and immunization in our recruit populations. And we have a plan for using history to update other vulnerable people in that setting.

The chlamydia prevalence. Lieutenant Colonel Neville is planning a prevalence study in

our population since we don't have that data, although we are looking carefully at the data that had been supplied by others in the Army and Navy.

We also have made the move this summer to put all of our beneficiaries in a military immunization tracking system registry. So we will have an immunization registry of all of our beneficiaries now. We did the active duty in 1998, and we have now picked up all other beneficiaries. So we will have that capability of tracking everyone.

We're also doing the individual medical readiness software, which will help us track our readiness needs. Just a quick update on Air Force-specific issues.

Any questions now?

COL GARDNER: Yes. I've got a few. I was on a conference call the other day with CDC. Were you on that one, too?

COL BRADSHAW: Yes.

COL GARDNER: In going back to all of the seven groups, it seems to me you'll require more than 2.8 million doses.

COL BRADSHAW: We are. Well, potentially it could be, but our historical use,

realizing that not everybody takes advantage of what's offered ends up being 2.8 million.

COL GARDNER: By quite a lot, right, because somebody elderly you are giving -- about one in seven, I guess, of people are accessing it through military, the elderly.

I guess my questions were a couple. One, would the military consider going in a different direction than CDC in terms of -- everyone would agree that the elderly and the mission-essential folks should be highest priority, I think. The question is: As you move down the list, what looks more like civilian priorities, where the strong consensus is to try to direct, as possible, vaccine that's available early toward the high-risk people, rather than the well people, which currently consume about half of the vaccine in the United States.

So yesterday, the roundtable discussion, how do you not give it to the 40-year-old healthy person and get it to the elderly or other people? And some of the groups further down your list were more in that category than the high list.

So one of the questions that occurred to me, would one consider a policy of stockpiling the

neuraminidase inhibitors, perhaps as an early -- there are two other facts. One was that we didn't seem to have a lot of early data from the surveillance system that there is a lot of influenza this year. The surveillance from Asia and South America that was reported showed relatively low levels of influenza at this time of year. So it doesn't look at this point that we're in for a big year, but that's preliminary data.

Secondly, there was a more optimistic report than previously about the ultimate availability of the vaccine and that this is more a delay than a shortage, but that was not a definite feeling. That was the consensus.

So the strategy I guess that occurred to me would be a couple. One, should we be stockpiling neuraminidase or something that might help in an epidemic situation should it hit?

Secondly, because we're only going to get a tenth of the vaccine that we're looking for on time because of the trouble with the Wyeth vaccine, would you consider a magnanimous gesture by the military in which you would prioritize to just giving the high-risk and the mission-essential folks but for the other folks you would release the

vaccine recommendations until availability?

You may not have a choice on that in order for it to be given to the high-risk civilians I guess is the other issue. You would take a chemoprophylactic more aggressive approach, whether by choice or become less aggressive for the lower priority groups on your list.

COL BRADSHAW: I think, as I mentioned yesterday, the problem for us is that one of our major manufacturers and contractors is one of those that has a problem with the delay. So it's almost a moot --

COL GARDNER: You may not have a choice on this.

COL BRADSHAW: It's almost a moot point. Our plan is I think to do our high-risk folks first if we can and a few mission-critical folks and then as vaccine becomes available, which is very similar to the CDC recommendations, then go with our more organized approach with lower-risk or individuals, which makes me think that we will probably be in a position of not necessarily being able to help out on the early side with the high-risk folks by shifting vaccine.

I mean, I think we do have, for

instance, with our trainee populations a plan of using antivirals possibly with them if vaccine is not yet available. And that's a contingency for that purpose.

COL GARDNER: Are we stockpiling the antivirals?

COL BRADSHAW: We have not made a decision to do that right now because, I mean, CDC doesn't really recommend them strongly in use. And I really think the only ones that probably need to consider that for our folks would be our training centers and perhaps -- you know, I don't know if the Navy has decided whether or not they want to use it for shipboard personnel, but it would seem to be unwieldy to do that. So it's outbreak control in my mind.

Dr. Ostroff?

PRESIDING OFFICER LaFORCE: Could I ask members to just introduce themselves before you make a comment for the record, please?

DR. OSTROFF: Steve Ostroff from CDC.

If I remember correctly, a couple of years ago when A Sydney came along, the vaccine clearly didn't work that particular year. In fact, if I remember, the military did vaccine efficacy

estimates of basically zero.

I'm wondering if you looked at your data from that particular year to help guide you in terms of your prioritization based on where you saw particular problems that year when essentially there was no vaccine either.

COL BRADSHAW: We did not. I don't know if anybody else did, but I know it did come up in our discussions.

Yes?

DR. ALEXANDER: I'm Linda Alexander. I had a question about your chlamydia prevalence study. Would you describe that a little bit? Are you doing males and females? And are you just looking at new recruits?

COL BRADSHAW: I'm going to defer to Dr. Neville. He's trying to take the lead on that for us.

LTC NEVILLE: Yes. We're still in the planning stages, but we do plan to look at females first and then males. It's a relatively small sample. It's almost more of a feasibility study for the basic trainees because the basic training population or the basic training time in the Air Force is so compact and full of stuff.

So to squeeze in a screening test and then to follow up for causes, contact tracing for females is a little bit of a challenge. So this is more of a feasibility, a very small prevalence study. I mean small numbers I should say, not the thousands that you see in the RME.

DR. ALEXANDER: Right.

LTC NEVILLE: If it works, if it's feasible and it works, then it may grow to doing it for all of the trainees as they come in.

DR. ALEXANDER: Are you saying that when female recruits come into the Air Force, they have a gynecological exam as part of their in processing?

LTC NEVILLE: No.

DR. ALEXANDER: No?

LTC NEVILLE: They should have had that at the stages before they arrive at basic training for their physicals to see if they're eligible for the military.

DR. ALEXANDER: And is screening done then?

LTC NEVILLE: I don't think so, not for chlamydia, no. In fact, I'm sure it isn't because that's just an exam. They don't have the follow-up

Pap smears and treat them if it's positive and so on because subsequent to that basic training, they go up to their technical schools and their first assignments and so on. And as those months go by, they'll get their regular Pap smears and so on.

At that point, then the screening could occur if it doesn't when they first come in as basic trainees. I don't think that's happening right now.

DR. ALEXANDER: I think what I find alarming is that it's such a missed opportunity. If we have regular gynecologic screening, it's a golden opportunity to do chlamydia screening, particularly in women. And that's what CDC has been recommending for a number of years.

So to find a standard of care in the military that's less than the standard of care in populations across the U.S. is something that I find that's disconcerting.

LTC NEVILLE: I agree.

PRESIDING OFFICER LaFORCE: What if we come back to the -- this is a point, by the way, that has been made before and one that continues to bother some of us, this issue about what we do really ought not to be any less than what is a

standard in the civilian community.

The second issue has to do, again, with these antivirals and the question: Is there going to be an effort, Colonel Bradshaw, to either have more thought or more reflection about this issue?

Because I see a couple of problems. One, I see tremendous pressure being brought to bear. Let's assume that the worst happens, that an epidemic does follow and there are real shortages. I would think in terms of just the issue of military preparedness, that's a big, big deal because of the chaos that --

COL BRADSHAW: There have been extensive discussions on the issues of antivirals. And we have also developed a paper with guidance for their use. But there are issues.

For instance, the amantadine and rimantadine have a fairly high incidence of CNS side effects, about 12-13 percent with amantadine. I think it was, what, about six percent perhaps with rimantadine.

PRESIDING OFFICER LaFORCE: Okay. But that's age-specific and much higher in older age groups.

COL BRADSHAW: Right. For instance, in

flying personnel, we can't use it. So, I mean, then you're looking at the more expensive drugs, which are significantly more expensive, like neuraminidase inhibitors.

But those, for instance, are, at least in terms of what their actual package insert is for is for treatment, not prophylaxis; whereas, we think that prophylaxis is the main use that we would have for these in many respects.

PRESIDING OFFICER LaFORCE: One is licensed, I believe, for prophylaxis.

COL BRADSHAW: I don't think it's licensed yet. Nijon published an article where they used it for prophylaxis, but it's not licensed. And the package insert doesn't state that, to my knowledge. In sultramavir, there is an article that showed it was used for prophylaxis.

COL WITHERS: I recently checked the PDR Online. And neither one said that it was licensed.

COL BRADSHAW: And also the CDC documents and recommendations state the same thing.

DR. OSTROFF: I don't know to what degree it came up on the call yesterday, but we had the experience with the avian influenza problem a couple of years ago in Hong Kong of looking to see

whether or not how much amantadine and rimantadine was available. There's not a lot available.

So there is going to be significant pressure. If it needs to be used, there's going to be a lot of people competing for that drug.

COL BRADSHAW: And at the CDC level, they're talking about stockpiling the raw materials, other issues like that, enrolling stock. All of those issues are being discussed, even at the national level. But at least in the conversations that I participated in recently, they continue to downplay the role for antivirals. We think we have some certain populations that we would have a use for them, though.

COL GARDNER: And particularly in years where the vaccine doesn't look very effective, it seems to me that's all you've got. In terms of military preparedness, I would think there would be a very special case to be made for stockpiling neuraminidases.

COL BRADSHAW: It could be a consideration.

PRESIDING OFFICER LaFORCE: Bill?

DR. BERG: Bill Berg.

Colonel, if you end up using the

neuraminidase inhibitors prophylactically, how will you handle the issue of informed consent?

COL BRADSHAW: Well, that's the problem.

DR. BERG: I think the literature clearly supports this, but based on the Desert Storm experience, there was a lot of outcry afterwards about using these so-called experimental drugs.

COL BRADSHAW: Exactly. That's exactly the problem, why I brought up the distinction, because it would have to be done by IND if we did it as a policy. We could probably skirt the issue by saying the individual providers could take their usual judgmental discretion and prescribe them, but if we did it as, say, a health affairs policy, then it would have to be by informed consent.

PRESIDING OFFICER LaFORCE: Yes, sir?

CAPT SCHOR: This is Ken Schor. From a Navy perspective, -- and I'll speak for Wayne McBride also since I just chopped a message that's going to go out as a heads up to everybody in the naval services -- there is a two-pronged approach for this.

One is to the hospitals, to tie that in to the providers, let them make the decisions on

the individual patients, who have high-risk conditions and made neuraminidase inhibitors.

On a population approach, we're planning to tie that into the preventive medicine units and tie that in to an outbreak response so that as concerns about a possible outbreak based on surveillance, outpatient surveillance, on ships or with Marines indicate an increase in prevalence of ILI in a week, that that should alert the PrevMed units.

And they should then have some level of control over rapid diagnostics, which based on sensitivities and issues with prevalence, they can sort through those issues and also sort through the indications for starting prophylaxis.

In general, we have a sense that there is a very low need. Even if there is a limited outbreak, this just wouldn't be used that much. We don't see that the young active duty force would either: one, comply with taking it or that the commanders would see a huge need to take that unless there was a ship very much, say, in the Persian Gulf and Saddam started doing crazy things and they were very much on the hook to do something. That might be a very specific case.

With potential side effects, the technology that they have at their disposal that they have to have their full faculty, even if they're not flight crew, they're what standing abilities are very critical to us.

COL BRADSHAW: I should also mention that we do have a surveillance plan in effect as well where we're using the Naval Health Research Center with their respiratory surveillance at the recruit centers and then the Project GARGLE. And we're adding some Army posts and so on to our surveillance net. So we're going to be looking very carefully at that and also having people do syndromic surveillance in the facilities.

One last quick thing. I would just want to introduce Lieutenant Colonel Vic MacIntosh. Vic is a new preventive medicine officer that is going to be working with me. Unfortunately, we have the Military Veterans Health Coordinating Board that is meeting simultaneously. So some of us are going to have to leave and go participate in that, but Colonel MacIntosh will be representing me at the AFEB.

So thank you.

PRESIDING OFFICER LaFORCE: Thank you,

Colonel Bradshaw.

Yes?

LTC MacINTOSH: If I might just add one clarification on chlamydia screening? What we're trying to do is establish chlamydia screening right when they come into the service, which is a little bit hard to do because of the time presses on.

That is not to say that chlamydia screening doesn't occur once the trainees get to their bases. They're just more dispersed. And then it's more of an MTF-specific, provider-specific issue, rather than an Air Force programmatic screening for everybody.

DR. ALEXANDER: It's actually a reported condition at the local --

LTC MacINTOSH: Yes, ma'am.

COL DINIEGA: This afternoon at 1315, Dr. Charlotte Gaydos will be presenting some findings on the chlamydia study.

PRESIDING OFFICER LaFORCE: Capt Schor?

CAPT SCHOR: Thank you. If I could have the slides, please? It's "AFEB HQMC." Good morning. I'm Ken Schor. I work at headquarters, Marine Corps Health Services, as the PREVMED officer. And Wayne McBride is not here this

morning. He asked me to let you know that he is deferring his time to Colonel Bradshaw, who was just up before me.

And I would like to let you know that he is probably in his twilight month. He should transfer next month to a local naval hospital and work as a clinical epidemiologist.

We do have on good intel that his replacement, Captain Select Jeff Yund, is inbound from Pearl Harbor, which is Preventive Medicine Unit 6, and was seen yesterday in Montana slowly headed in an easterly direction. And he is due in at BUMED sometime in the beginning of October. So they're in the midst of turnover right now, but Commander McBride, as always, sends his regards to the Board.

If we could go back to the first slide? That's the N slide. Keep going. While he's doing that, I'd like you to stop on denominator medicine.

Let me do a little segue. I haven't talked to Colonel Bradshaw with this. The issue of flu vaccine distribution, I will tell you that probably the key issue and from our perspective in the Marine Corps and my boss' perspective is this is a SECDEF decision.

Even though Admiral Clinton has gotten out in front of this issue and is working this issue and will brief it up through the DEPSECDEF of Personnel and Readiness, Dr. DeLeone, we kind of feel that this is probably going to reside in SECDEF because he is national command authority.

The real issue to us is: Do you really give it to the war fighters or do you set it aside for the medically high-risk? And it looks like the Marine Corps position is very divergent from what has been worked on in the Joint Preventive Medicine Policy Group, which I was a part of and I bought into.

I'm being told to take a different position by my bosses back in headquarters, and that is our primary job is readiness. Our primary job is war fighting.

Our active duty family members and our retirees will understand if they can't get vaccine. They may not like it, but they understand that active duty and readiness come first. That is number one and number two on all service chiefs' plates. They're probably testifying this week to Congress on those very issues. And, as we all know, it's an election issue.

So the Marine Corps position is it doesn't go to active duty family members as much as we would like it to go to them. It's only right now 270-some thousand, 240-some thousand doses. That doesn't even cover the active duty forces.

I'm well-aware that there are some war-fighting CINCS out in the hot spots who would like to have all of the vaccine for all of their forces in theatre. That's over half of the current DOD supplies in hand.

Now, this is hard to swallow as a physician and as a person who cares, as a family physician originally, but I think it's probably maybe the right thing to do.

If U.S. government wants to invest its money -- this is my personal commentary. If they want to invest their money in readiness and in the military, maybe we've got to put our money where our mouth is and put it toward readiness.

Granted, we don't know what the impact of influenza is or the effectiveness of the shot, but certainly the Marine Corps forces, 70 percent of the Marines are there on the front line and ready to go at any time. And maybe we need to back that up.

It sends the wrong message to put 20 to 30 percent of the vaccine, only 20 to 30 percent of the vaccine, to active duty forces, the rest to medically at risk.

Now, I realize -- and I know we have some members of the Board who work in local county health departments -- that the way county health departments do business makes it a lot more difficult to walk in and get a shot if you have health care coverage somewhere. My understanding is locally in Montgomery County, that they carve out and only cover folks that don't have any care.

So there are some real issues here about the overall public health infrastructure, but this is a diversionist's view that's being formed in my shop. And that's just the position we're probably going to take on this whole issue, which may be counter to the other services.

And it may be supported by feedback that comes in through the Joint Staff because they're staffing up through their own channel. And I think Brian Balough will mention that briefly after me. So I just wanted to do an aside on that.

If I could have the next one? I just wanted to mention three things that are of some

interest. They're very divergent. I avoided the use of population health on this slide because I think in DOD, that tends to be linked to disease management, rather than what we in preventive medicine would see as population health.

There's an interesting thing. As many of you may know, the TRICARE is coming under the vice chiefs of the services. They are heavily engaged in something called the DMOC, the Defense Medical Oversight Committee.

Those are sort of the vice presidents of the services, so to speak, the four-stars. And they're heavily engaged in this process, and there are some big concerns about contracts and money shortfalls. Some of these shortfalls may cost more than any of the most expensive weapons systems we're trying to buy, like the new fighters and new missiles and things like that.

So they're finding that one of the difficulties, as many of us confront health care systems, is: If you can't precisely define your denominator, people you're taking care of, how do you figure out what your budget ought to be? And so that was pointed out by some high-paid consultants. The service chiefs said yes, that's a

pretty good idea.

So one of the interesting things is that maybe much of this effort is focused on the hospitals. Well, those of us in the naval services and other services have the operational side, work out of aid stations, work out of gray hole ships, things like that.

We very much understand population health. We understand very clearly what our denominator is. And it's just a little point to that effect. If we understand our denominator, I think we understand how to execute population health within a very tight budget. And perhaps the hospitals and the DOD can learn something from how we do population health.

So there is a lot of convergence in this area between hospitals and the operating forces. This is one area that there may draw some strengths from the operating forces.

Next slide, please. Our office is heavily engaged, even though we have one admiral, four 06's, including a dental officer, and four enlisted.

This next issue is something that is quite interesting. The Assistant Commandant of the

Marine Corps said: We've got to get better on safety. And so he started a safety campaign about four months ago. You see the three top main features.

He started an Executive Safety Board. This is very top-down, getting the idea that safety is a leadership thing. So this Executive Safety Board is basically three-star level and above. They own the bases. They own the fighting forces. They're the main folks out there, main commanding generals.

One is to increase accountability, every Marine is responsible. One of the thoughts was like every Marine is a rifleman, every Marine is responsible for safety 24 hours a day, 7 days a week.

It's interesting. There are some thoughts that we are so good at teaching safe practice on the range and when we do operational things, that maybe when Marines go home, they let their guard down too much. It's not so tightly woven into everything they do. So this concept of 24 by 7 safety may need to have a little bit more attention to it.

One of the efforts that's ongoing is to

integrate something called Operational Risk Management. I am not an expert on that, but it simply gets to ask the question of: When you do a practice amphibious assault at night with night vision goggles and 2,000 Marines from 100 nautical miles offshore and you have planes, trains, and -- well, certainly not planes, trains, and automobiles, but you have little boats in the water, you have helicopters in the air, and you've got a lot of things going in a very compressed schedule, are the commanders responsible for asking the question of what are the risks and how are we mitigating those risks?

That's kind of hard to ask that question when you're thinking about even exercising a war-fighting plan. So we're trying to get that integrated at all levels, all the way down to the platoon commander level.

And then this final thing is some little avenue that I sort of elbowed my way into. They hosted something called a safety forum. And they had safety experts from industry and federal government, NASA, AAA, other industry groups. And they're all safety folks. I was the only physician on board there. I was the only preventive medicine

officer.

It was quite interesting. So I had to elbow my way into that. And, as a result of that, one of the key issues is the Marines are trying to get a handle on how many Marines are lost per year to musculoskeletal injuries.

We know that those kinds of injuries are fairly prevalent, that there tend to be a lot of overused injuries because of the intensity of the physical therapy or physical training, and hiking and other evolutions that go on for preparing for deployment and their operational roles. But you know what? We can't really tell you how many Marines are lost a year to musculoskeletal injuries.

Now, this gets wrapped up into difficulties with manpower personnel databases, with VA codes, which I'm only beginning to understand, which have to do with percent compensation. But what we're trying to do with the help of a USUHS PREVMED resident is to try to estimate and get a sense of the landscape of this loss to the Marine Corps.

One thought is it may be around 2,000. We're trying to take those that get essentially

either a retirement due to physical disability or separated for physical disability reasons because they can't continue as a Marine.

I'll be happy to give you updates as that effort goes along. It will require linking both manpower and medical databases. So that's just a little interesting issue in trying to get into the area of injury epidemiology.

Next slide, please. One final thing. I've had the privilege of starting to get involved with this effort. Many of you at the local level recognize that weapons of mass destruction are a planning future for you.

There is a lot of concern about all sorts of weapons of mass destruction. And there is some concern about the role of the military in this. There is also a recognition -- and this was brought down by the President in a decision directive -- that if another Oklahoma City or a chem/bio weapon or a radiation incident occurs, that this will rapidly get national attention and that the public is likely to demand very rapid response by the military. So that raises some real interesting issues with the Stafford Act, with *posse comitatus*, and what you can use military

forces for in the United States.

By directive and working down through the Joint Staff, we're finally trying to put these ideas on paper by bringing the experts from FEMA, from FBI, from State Department, from Red Cross, from all the players in the services together to try to figure out how to make this work quickly and to put together an operational plan, an O plan, as we call it.

Normally those are the war-fighting plans that are locked up in a safe somewhere. This is an unclassified effort, but it's to bring those folks together and to try to figure out how to respond domestically to such an incident and just to recognize that any DOD response -- I hope this goes without saying, but it needs to be emphasized all the time that DOD will be in support of local and state authorities on these incidents. I just wanted to bring this to the Board's attention that this is an effort that's being chaired by the Joint Staff.

The final slide, just a little plug you may have seen. James Bradley, if you ever get a chance to hear him talk, he is the son of the hospital corpsman or the pharmacist mate, who is

John Bradley, right here.

He claims that this photo is the most famous photo in the world, and it's a wonderful book. And it gives you some sense of he had entre into these families that no one else will have because he is the son of a flag-raiser. It gives you some insight into the Marine Corps.

It hasn't changed a whole lot in many ways in 50 years. And if you read the Post today, there's an interesting thing about a GE executive that got to spend a week with the Marine Corps, he and his son. Other services are doing that.

So, with that, I'll take any questions.

PRESIDING OFFICER LaFORCE: Steve?

DR. OSTROFF: I remember from the -- Steve Ostroff from CDC -- top-off exercise earlier this year, where the -- for those who don't know, the top-off was the simulation of a simultaneous biological and chemical and radiologic attack in various places. The big episode was a plague outbreak in the Denver metropolitan area.

One of the issues that came up very quickly was taking care of mass casualties with the medical care system quickly becoming overwhelmed. The state very quickly turned to the military to

assist in that particular area and found out that the medical assets couldn't deploy as rapidly as they would have anticipated that they could have deployed.

I'm wondering if you all are talking about that particular issue in regard to weapons of mass destruction.

CAPT SCHOR: I think that is going to be a very critical issue. Where we are with this is this is very much on a fast track. They've got about two months to get at sort of the over-arching directive that says, "We will do this and move in this direction."

The operational plan is going to get started toward the end of this month. And that's supposed to be wrapped up before the holidays. There is something in an operational plan called an Annex Q, which is the medical plan. That's going to be a very robust part of that that will be working along the federal response plan in the military, trying to figure out how to support the Red Cross in its key role in mass care and a recognition I think that that is going to be a very important component of that Annex Q medical plan. So yes, that's very much top drawer.

The joint task force civil support that looks at this issue that is a response of about 60 folks last week was having very aggressive discussions due to that top-off exercise about mass care.

PRESIDING OFFICER LaFORCE: Yes?

DR. LANDRIGAN: Phil Landrigan from the Board, Mt. Sinai School of Medicine.

Let me offer a comment on your very interesting discussion on injury epidemiology. This comes from the fact that for the past ten years or so, I have served on a joint labor-management health and safety committee that advises one of the big three auto makers, Daimler-Chrysler.

And one of the things that the auto makers have seen, like so many segments of American industry in recent years, is currently the weeding and the most rapidly growing cause of morbidity in the workplace is repetitive strain injury, which in some of the plants had prevalence rates as high as 20-25 percent. Hopefully nothing is that severe in the Marine Corps. People doing operations on the line, operating the same wrench hour after hour, day after day really became a huge problem.

They started with the kind of approach that you have outlined, trying to refine surveillance techniques, get definitions, plot the course of the outbreak, which was all useful as a first step, but it wasn't going very far to control the thing.

What they finally did -- and it seems now to be making a difference -- is that they have basically made the plant manager the owner of the epidemic in his or her plant so that each year when that guy gets his fit rep, one of the things on which he's judged is whether or not he has done an adequate job in controlling the epidemic.

So the medical officer becomes an adviser to the plant manager, but it's the manager who has the line responsibility for controlling the outbreak. In other words, the locus of control is taken from medical and given to line and, most importantly, being made a basis for evaluation.

I don't know all the nuts and bolts of it. I'm sure there's a great deal of thought given to the details. But I could certainly put you in touch with the vice president at Daimler-Chrysler, who has orchestrated this. He's a really neat character you might enjoy talking with.

CAPT SCHOR: You know, the Marines like good solutions that are effective. The white paper that went out to all of the generals clearly holds them accountable. And it's part of their evaluation. They have to also move the analysis of incidents that we call mishaps that are very strictly defined based on level of injury or cost or other factors. Move that analysis along in a very professional and rapid manner so that it can't be sat on at a lower level.

How quickly that is going to get below the general officer level remains to be seen. I think that's going to be the next step, but it's very clearly a leadership issue, not a medical issue.

The problem is I've got to get the door open a little bit sometimes, say, "We have a little bit to offer here." So they're moving forward, and they're sort of taking the -- for instance, one of the issues is seat belt use.

Fifty-five percent of motor vehicle fatalities, Marines aren't wearing seat belts. Now, they wear seat belts in tactical vehicles. They wear harnesses and all sorts of other protective gear. For some reason, they're not

wearing seat belts in their cars.

Well, now we recently got the ability to prosecute any Marine anywhere in the country, not just on base, for not wearing their seat belt. So if it's off base, they yank them back on board. And the punishment is much more severe through the military system. That is a new thing that just got worked out by the legal officers.

They're working on the negative reinforcement aspect of it, which is pretty good. The civilian safety folks said: Hey, we've got to be a little positive here. So we've got to balance that stuff out and work with some of the medical and estimating things.

I appreciate your input, sir.

DR. LANDRIGAN: There was a bit of that negative seven or eight years ago at Daimler-Chrysler. You may recall they got something like a $15 million fine from OSHA for failing to report. That got their attention.

PRESIDING OFFICER LaFORCE: Rose?

DR. SOKAS: Rosemary Sokas.

A couple of years ago, the Board actually went to Parris Island and had a wonderful experience there. One of the most striking stories

was really looking at pelvic stress fractures that occurred among the young female recruits because they were marching at the back, instead of in the front. When they switched that, they, as I recall, eliminated the problem.

It seemed to me it wasn't clear, in retrospect now, whether that kind of on-site evaluation and feedback and information being fed back to the decision-makers was built in or whether that was the result of somebody doing a study somewhere. I don't know if local information going back to the commanders is available or is part of what is being developed.

CAPT SCHOR: I would say outside at -- you know, the training environment is sort of its own world in many respects. And that has become much more institutionalized.

They're very good at injury prevention and response. The primary prevention always needs a lot of work in that environment. The secondary prevention is pretty high-tech. They have training pools and things like that, but they're trying to not break those new recruits as much. They're really trying that.

In the operating forces, say, beyond six

months of service, as they get into their technical specialties and not with the operating forces.

The local feedback probably isn't there. Yes, it's a very good point. The local feedback probably isn't there, and we probably need to begin to build that in. That's one issue with getting the local disease non-battle injury surveillance.

And the injury fields on that, the three fields on that, that I think can be very powerful and a great way to get better acceptance of doing local surveillance out of the aid station levels, then even just looking at diarrheal disease and things like that, this issue of injury prevention has more visibility than almost anything else in the Marine Corps. It's number two on the Marine Corps' list of importance right now.

PRESIDING OFFICER LaFORCE: Before we finish, I have no problems with the decision in terms of priority for war fighter in terms of a decision made to prioritize vaccine use in that direction.

The only plea that I would make is that I think you really might want to look at the -- if that is the strategic; that is, the readiness of the war fighter, I think that you might want to pay

a bit more attention in terms of the chemo-prophylactic end of things as well.

Investing a little bit in that direction would provide you assuming there are going to be real shortages with a flexibility that you will not have if you simply rely on vaccine. That's the only point.

If a decision is made in terms of readiness of the war fighter, I think just simply having that option allows you as a preventive medical officer or as a general in charge of a brigade or whatever of Marines does give you some preventive medical flexibility that you just don't have if you don't have those in the zur. That's all.

CAPT SCHOR: Sir, the only thing I would say in response to that is it's very difficult to figure out if you're going to put that on every ship.

DR. SOKAS: See, I think what Marc is saying -- let me just ask a clarifying question -- is that this ought to be a research, a preventive medicine research, project that is undertaken this year.

This is the perfect year for it. And so

you might implement it with IRB approval, with informed consent, in some locations and not in others, to really demonstrate the utility in the field.

PRESIDING OFFICER LaFORCE: I think that for each one of these challenges that is occurring, these are challenges in terms of a flu vaccine shortage. So they're going to challenge the civilian sector, the military sector, everyone.

This isn't going to go away. I mean, flu virus is going to continue to mutate, et cetera. The plea that I would make is to think of this in terms of a case study and to really sort of reflect on and hopefully -- you know the vaccine manufacturers. Everything will come along. And the vaccine will be very effective, and everything will work out. But one of these years, it's not. And it might be an opportunity to really invest a little bit of thought in terms of saying, "Gee whiz."

How would we approach this if we were really stuck within these particular limitations and something did go wrong in the Middle East? I think, again, I would just simply make a plea not to sort of truncate your preventive services'

decision and just simply say, "Well, this might make people a little goofy. Therefore, we're not going to have anything to do with it at all." I think that's being a little tough in term of the whole issue of chemo-prophylaxis.

Yes?

COL GARDNER: Just to follow that, another issue, about every 40 years, we get an influenza virus that attacks young people. And if we happen to run into that plus a poor vaccine match one year, you would certainly wish to have -- it seems to me the chemo-prophylaxis would suddenly be a very important only response.

I agree that it would give you some flexibility, even if it's not a first-line defense at this point. It's not too tough, too far-fetched to think of a year where not only might we not have a good vaccine match, but we might have one of the more aggressive youth, younger person thing, such as 1917 and 1957.

PRESIDING OFFICER LaFORCE: Okay. Let's move on. Major Balough?

MAJ BALOUGH: Thank you, sir. Can I have those slides, please? I'm just going to take a quick minute, few minutes, here and discuss what

the Joint Staff is doing.

Yes. Please put the slide on. It should say, "Joint Staff" or "AFEB Update." I'm not sure how you saved it. I can do it without the slide anyways.

The first issue is the anthrax refusal policy. We're going to get an update from Colonel Grabenstein on the Anthrax Program. The only thing I wanted to talk about is we are staffing with the CINCS and the services right now a refusal policy that basically will collect the information so that the information will go up to the Secretary of Defense so that he can report that to Congress. What that policy is going to -- right now what it states is "You are considered a refusal when you are discharged from service."

The previous policy required us to report a lot of information: name, rank, Social Security number, unit, what happened, and that's a lot of undue command influence on the UCMJ, Uniform Code of Military Justice, program.

So what we have taken the approach is if you refuse to take the vaccine, then the chain of command can counsel you, can give you an Article 15, can do all of these things? Well, you're a

disciplinary problem at that point?

Whenever you decide not to take it again and we subsequently discharge you, then you are a refusal. That's the way we're trying to get around the legal issue of command influence.

On the influenza policy, we have talked a lot about it. One of the questions came up with is the operational requirements. The first time we went out to the CINCS with the policy, the influenza plan, the Joint Forces Command came back with a requirement of almost 100,000 doses.

And CENTCOM and Korea also said that they wanted all of their forces vaccinated. If you throw in the rest of the CINCS that had their small pieces, we wind up close to about 160,000 doses. So that's the majority of the 230,000 doses that we have on hand.

That policy is being staffed right now. We expect replies back from the CINCS on Wednesday, tomorrow. And we'll get feedback to Health Affairs on the CINCS input.

DODI 6205.4, that was signed in April. And it was posted on the defense link. What that is is it's a requirement for the CINCS to develop plans for how they will administer immunizations

for other than U.S. forces, nonmilitary, the contractors, the civilians, that are in a theatre of operations for consequence management. And they are developing those plans.

CENTCOM has got a good plan right now. It's in draft. We're sharing that with the other CINCS and expect that will come back in October. Then once that's back, we'll review it. The Joint Staff then send that back up to OSD for their review.

The Military Veterans Health Coordinating Board, that is chaired by Major General Claypool and Admiral Mayo. The reason why Admiral Mayo and Colonel Kimm are not here is Admiral Mayo is the Chair for the Deployment Health Workgroup and Colonel Kimm is the secretary for that. So that's why they are not here at this time.

I don't want to take up any more time. Are there any questions?

(No response.)

MAJ BALOUGH: Yes, sir?

PRESIDING OFFICER LaFORCE: I'm sorry. This went a little fast. The DODI, the immunization, --

MAJ BALOUGH: Yes, sir.

PRESIDING OFFICER LaFORCE: -- could you describe that a little bit more?

MAJ BALOUGH: The DODI, it's for consequence management operations. Say we've got a country and we've got to evacuate, basically do a noncombatant evacuation.

PRESIDING OFFICER LaFORCE: Okay.

MAJ BALOUGH: The first priority is to try to evacuate everybody. If we cannot evacuate them, then what are we going to do to protect the U.S. population that's there, the contractors, the host nation workers that are working for DOD in support of our operation?

It's basically the CINCS have to go in and identify how many of a lot of different categories they have, identify their population, in essence, and identify guidance.

Right now they have to identify the guidance that they will put out to whoever is going to be the joint task force commander, that they have to implement the following procedures in order to take that population into consideration and how they are going to protect that population if we cannot evacuate them.

What CENTCOM is doing right now is they have developed an appendix to the Annex Q, which is the medical annex, that will go in. And that is directing that all of the services -- they have broken down their region of the world by countries. And each service has a certain country or a number of countries. They're responsible for planning all of the operations in that country.

Now, the other CINCS have not broken that out like that. They're just going to put guidance that whenever we have a joint task force stands up. These items have to be considered.

In identifying what immunizations are out there, really it's anthrax at this point. But looking further on down the line, when we get smallpox approved and we have a stockpile for that, then how are they going to use that?

It looks at the recordkeeping requirements. If DOD is going to give a civilian an immunization, we've got to keep a record for it. And it gets into those types of things, sir.

PRESIDING OFFICER LaFORCE: Thank you. Good.

Commander Ludwig?

MAJ BALOUGH: Thank you.

PRESIDING OFFICER LaFORCE: Preventive medical officer for the Coast Guard.

CDR LUDWIG: Good morning. I have a presentation, too. I gave the disk to AFEB. However, you all also have a handout. So I'll go ahead and start.

Just to introduce myself, I am Sharon Ludwig. I have spoken in front of this Board on several occasions, and I know a good number of the people in this room. Just to let you know, Commander Tedesco reluctantly but appropriately passed the AFE torch on to me as the Coast Guard epidemiologist.

The topics are listed on the second slide on your handout. Do you have the presentation at all back there? Okay. The next slide shows the topics. I won't read it back to you.

The next slide. We have already spent a great deal of time on influenza, but I just want to give a little bit of Coast Guard perspective to this.

This was to be the first year for our new requirement, which I worked to have approved, which was to have all of our active duty required

to have influenza vaccine. Previously only alert forces, whatever that was defined as, were the ones who received the vaccine. And I didn't feel that that was appropriate. So it was one of the first things I worked to get changed, and it was agreed upon. Then we were faced with this shortage/delay of the vaccine.

On the plus side, we do have a very, very small high-risk population in the Coast Guard because neither the Coast Guard nor the Public Health Service, of which I am actually a member, has hospitals. So our high-risk population go elsewhere, somewhere else than the Coast Guard facility, for their care usually. We have a few, but it's relatively a small group.

We also have, in addition to no hospitals, no labs. And I shouldn't say "no labs" but no high-level labs. We have some basic and intermediate capabilities, but all of this will have an impact on whether we can use rapid diagnostics in order to utilize the antivirals for treatment, for instance.

And we have worked closely with the DOD through the JPMPWG, another group that I'm a member of, so that all of our policies are in synch.

We do have also in the Coast Guard, I think uniquely, a relatively large, perhaps half of our population, outside of a military MTF catchment area. This means that we don't really have control over whether they receive the vaccine or not. If they go to a civilian provider, they're going to be under civilian-type rules for whether they can get the vaccine or not. I consider this a readiness problem.

The next slide talks about some of the operational issues in the Coast Guard that are somewhat different from the other services, the other armed forces. We do have fewer personnel in what we are considering for our influenza plan and also in general our military strategic areas, like South Korea, where they need to be ready to enter a conflict of perhaps large proportion immediately.

However, we do have a great number of people. In fact, most of our Coast Guard personnel need to be immediately ready every day, every hour. And, in fact, they need to be always ready, or *Semper Paratus*.

They go out daily to save lives, environment, and property and enforce laws on various things that have to do with environment,

immigration, and smuggling. These missions together give them a very large civic responsibility on a daily basis.

And if you'll remember from the CDC recommendations in their annual flu statement in this sort of general population category, they talk about the importance of vaccinating those who have important civic duties to minimize the disruption of essential activities during outbreaks.

So, even though we have what looks like a small readiness issue if you compare us to the DOD, we do have, actually, a large readiness issue just in and of our daily mission. So this is as big of an issue to us as it is to the civilian world and the rest of the armed services.

Next slide. Our febrile respiratory illness or ARD surveillance -- I'll give up the old acronym with difficulty. ARD is what I grew up with, but FRI is what I'm getting used to.

We have ongoing FRI surveillance at Cape May in cooperation, well, really, with total help of the Naval Health Research Center in San Diego. They are providing all of our laboratory support, and we appreciate it very much.

We had some decreased vigilance during

the spring and summer. They are, like so many places, short of personnel. And they kind of let things drop off. And then, lo and behold, we had an adenovirus outbreak. Only we didn't know, of course, at first that it was adenovirus. But we were concerned.

All of a sudden, I got some data, and the rate was very high. I said: Something is going on here. And what if it's influenza? And it was just about the time we started talking about the influenza shortage, and there was word of an influenza outbreak in Texas, I believe. And so I thought, you know: Let's get on this right away. The up side of this is that there was a great deal of increased vigilance and attention paid to FRI surveillance.

The next slide shows -- well, the light blue color is the rate of FRI per 100. And you can see where it goes above -- can you see it from the back, the light blue line? I'll use a different color next time. Okay.

Well, anyway, it does go above the red line in August, I think. The thing is August 6th or a little bit before that. The dark green line is just a frequency. It's a number of positive

adenovirus cultures. But I think it shows pretty clearly that our FRI rate is mirrored by the number of cultures that are positive for -- you can't take that too far. It's a frequency compared to a rate and so on. But I think it does give you some information.

Next slide. Our medical manual is our one large regulation in the Coast Guard, a commandant instruction that covers basically anything that is medical. We try to redo it every year. It's quite an undertaking.

This is the first year that I have had a chance to really address some very large changes that were needed in our medical manual. I completely ramped up or, let's say, reemphasized disease surveillance with some new reporting requirements and adjusted the reporting, the method of reporting, and so on.

So I'm hoping that we'll get some better surveillance data for the Coast Guard. Of course, this is going to take quite a bit of getting used to a new requirement. Actually, it's not a new requirement. It will be newly enforced.

And the other difficulty, of course, is that we have 50 percent of our population, like I

said, outside of the military system. So we won't be able to get very good surveillance initially from them until I figure out a way to do that.

I also worked on the tuberculosis program. At I think it was the last meeting or the meeting before last, you heard a presentation of an outbreak investigation that I did of a pseudo outbreak of tuberculosis.

And so I reviewed our tuberculosis program in the medical manual and with the recommendations that this Board put out and some of the work that we had done, put in that new information. And hopefully we'll see a difference and not more pseudo outbreaks like that, but we'll see.

Our HIV program also needed some updating. It still does, but I gave that a good start. Commander Tedesco as the aerospace officer in the Coast Guard is dealing with aviation medication and nutritional supplements policy.

The next slide is pretty much self-explanatory. There was a great bit of activity for a little while as we were sorting out how to deal with the slowdown. Right now things are pretty calm, but I have a feeling that we're

going to hear how that may be changing again soon.

Last slide. These are some things that I'm working on getting going now along with a great number of other people who are in this room. I am on the STD Prevention Committee, which falls under the PSHPC, the Preventive Health Services something. Anyway --

(Laughter.)

CDR LUDWIG: I'm sure somebody knows it. And I know it if I stop and think about it. Prevention, Safety, and Health Promotion Committee. The STD Prevention Committee is now dividing into smaller subcommittees that are really doing the bulk of the work.

I'm the Chair of the Surveillance Subcommittee. And we are working on getting together some policy recommendations to give to the PSHPC that then will come out from the Assistant Secretary of Defense for Health Affairs assuming that they're approved at that level.

We are getting together with a group from Henry M. Jackson Foundation to do the STD educational intervention at our basic training site in Cape May. That probably will be next spring.

And earlier -- the second bullet is

chlamydia and gonococcal testing at Cape May, which we're going to be working out with the Gaydoses and Hopkins.

So we're pretty excited about all of these projects, and I'll let you know how they go. Any comments or questions?

DR. OSTROFF: Yes. I'm curious. In looking at the epi curve on the adenovirus, you seem to be having a sort of a periodic escalating trend here. And I'm wondering if that correlates with the training cohorts and what you're doing in anticipation that it may go back up again.

And I guess the other part of my question is: Do you have any information or evidence to suggest that they're taking it with them when they go up there and spreading it to other Coast Guard facilities?

CDR LUDWIG: Let's see. I think there were three parts to that question. The first one is that you notice some kind of periodicity to the curve. First of all, let me mention these are only six months worth of data. And I have only a year and a half total worth of data for Coast Guard adenovirus or FRI surveillance. I, too, noticed a little bit of a periodicity. I cannot explain it

at this time.

The last question I remember was: Are they taking it anywhere with them? And without a good surveillance system, I cannot say that. I just don't know.

I can say that one of our advanced training sites at Petaluma in California is a place that we notoriously have high influenza rates. We have not -- well, I take that back. Influenza is what we have assumed that it is. And the reason that we have assumed it is because they have not had required immunization in the past.

We don't know that for certain. And last year when we had one FRI outbreak, I arranged to have some specimens sent to NHRC, but, fortunately or unfortunately, it kind of died off fairly quickly. And so we didn't get any specimens to them.

In the Coast Guard, people as a rule do not go straight to advanced training. They go out on a ship or into an assignment. And then they apply for their advanced training. And so it's not like they're all going as a cohort to one place or another where we can follow them. They are scattered immediately to the four winds.

DR. OSTROFF: Just in follow-up, is there anything that you can do in anticipation --

CAPT SCHOR: Oh, yes.

DR. OSTROFF: -- that you may be having another big spike in a couple of weeks?

CDR LUDWIG: I'm anticipating a big spike. And as part of our influenza policy, I'm anticipating a big spike of FRI due to adenovirus and/or, probably and, influenza.

As part of our policy, I am recommending that they take a look -- this is a sticky subject, but I'm putting it into policy, and we'll see where it goes -- that they take a look at the capability of opening up some bays that are closed so that they can house people in less dense housing situations and also that they can quarantine; that is, keep isolated, one company from another with the hope of not having any intermingling between the companies. There are typically six, seven companies there at a time.

I don't know if that will go over. I can tell you I have looked over their housing situation, and they don't have the required 72 square feet per person. I'm certain of that because they're bunked three high with the bunks

basically a bunk apart.

Now, that's even better than what they'll have on shipboard, but it's still a concern of mine that they are not within the requirements for basic training.

I'm not sure what influence I can have on that, but now that it's come to my attention and I am trying to plan for a large respiratory season, I'm hoping that I can at least influence the policy, if not the practice. And if the policy is affected this year, maybe the practice will be affected next year.

Other things in anticipation of a bad respiratory season are I'm working with the pharmacist on the issue of stockpiling antivirals. I also was looking into briefly -- and I wanted to make some contacts here -- about the enforced hand-washing activity that either does or did take place at Great Lakes Training Center for the Navy.

And there appeared to be from the studies that I heard, although I don't believe that's been published, the presentations that I have heard in the past, that it did have an effect on the transmission of respiratory illness or on rates of respiratory; association, let's say.

If anybody has other suggestions, please let's talk about them. Anything else?

(No response.)

PRESIDING OFFICER LaFORCE: Thank you.

CDR LUDWIG: All right. Thank you.

PRESIDING OFFICER LaFORCE: Ben, do you want to finish with comments from Colonel Warde?

COL DINIEGA: Yes. Colonel Andrew Warde sends his regrets. He is escorting his boss, a brigadier general who is the British military attaché, through the Washington, D.C. area, looking at the types of jobs that Andy is involved in.

He wanted me to just relay the fact that there was a problem with malaria in one of the deployments in the U.K. It was a short notice deployment. The decision to deploy was done. It was 5 May, and deployment started 7 May.

And it involved 4,500 personnel being deployed as a result, malaria chemoprophylaxis, which should have been mefloquine, couldn't start until they were deploying for after arrival in country.

They have so far confirmed 70 cases of malaria, all but one of them being falciprim. And then in a follow-up operation, training operation,

involving 750 troops, they have identified 7 additional cases so far. He will update the Board at the next meeting on what the results of the investigation show.

I also have a few more other updates, but I will fill it in as speakers get up to get ready to give their talks.

PRESIDING OFFICER LaFORCE: Where was that?

COL DINIEGA: They went to Sierra Leone. I'm sorry. Sierra Leone, not to Hawaii.

PRESIDING OFFICER LaFORCE: Sierra Leone is not a very healthy place right about now for many reasons.

Questions? Comments? You know, I am going to propose that we take our break now because the next two talks relate specifically to adenovirus, the epidemic at Fort Benning and also the losses in terms of adenovirus.

COL DINIEGA: Just one announcement before you take your break. Try to stay to 15 minutes. The restrooms are across the hall here. And the cafeteria is down the long hallway, past the double doors on the left.

PRESIDING OFFICER LaFORCE: Be back in

about 15 minutes. Thank you.

(Whereupon, the foregoing matter went off the record at 9:30 a.m. and went back on the record at 9:50 a.m.)

PRESIDING OFFICER LaFORCE:

OUTBREAK OF ADENOVIRUS - FT. BENNING

DR. DuVERNOY: Hi. Good morning. My name is Dr. Tracy DuVernoy. I am a research epidemiologist from the U.S. Army Center for Health Promotion and Preventive Medicine.

This morning I'm going to describe an outbreak of Adenovirus Type 4 that occurred among infantry recruits at Fort Benning, Georgia in late April to early May of this year. Unfortunately, nobody told me that the acronym ARD was switched to FRI. So all of my slides will say "ARD."

Initially I will describe the process of the outbreak investigation, then discuss a few reasons why the outbreak occurred. And then I'll end with some control measures recommended by our epidemiology team.

Next. There is an organized protocol for performing any outbreak investigation. And although everyone may have their own guidelines, these are the basic steps that I will discuss in

following and performing our outbreak.

Initially what we did is we got some background information about what was going on. We then had to verify the existence of the outbreak. Then I'll describe the epidemic in terms of person, place, and time.

And then we formulated and tested hypotheses according to how the outbreak may have occurred. Then we'll talk about instituting control measures. And then the last step is to disseminate information to interested parties.

Next. Now, the background planning that we were aware of, we were told that 70 infantry recruits were seen at Martin Army Community Hospital in the ER with complaints of febrile respiratory illness on April 27th, 2000.

Primarily one battalion seemed to be affected, and they were from the Sand Hill training area. And that area is where infantry basic training occurs.

No deaths were reported. At that same time, 25 ill recruits were tested with 2 different types of influenza quick tests. They were nasal swabs.

And 23 among those 25 were positive for

either A or B. But we then, of course, had to consider other differential diagnoses, even though these influenza quick tests were positive. And some other considerations were adenovirus, parainfluenza, coccsacchi, and strep.

Due to the overwhelming, quote, unquote, "evidence" of the quick test results, we were then contacted by Martin Army Community Hospital, by the med program to come down for assistance. And so our EPICON team was contacted on April 28th of 2000.

Next, please. Our EPICON team consisted of individuals from CHPPM, Lieutenant Colonel Brian Feighner, myself, and Nikki Jordan. And then we also had a PREVMED resident, Major Rodney Coldren, who was finishing his residency at the time. He came from WRAIR.

Then we also had individuals from Martin Army Community Hospital, specifically Bryan Alsip. He was the chief of PREVMED. And then we also had a family practice resident: Rodney Gonzalez. Mr. Richard Townsend is an industrial hygienist, who helped us collect some samples; and then also Sandra Williams. She's a nurse, and she also helped with laboratory specimen collection.

Next, please. This is a map of the Sand Hill training area. And this is where basic infantry training occurs at Fort Benning. Individuals are processed at 30th AG, which is in the upper left. And they're there for generally one to six weeks, where they are immunized and they're given a bicillin injection unless they're allergic. And also various other testing procedures are done: HIV testing, blood typing, et cetera.

They are then sent to an opening in any of the units. Now, initially when the outbreak occurred, we were told that cases originated in Battalion 2/47, which is in the middle of the screen. Five ill recruits were tested with the influenza quick test. And four of them were positive.

We then heard that cases were occurring in the 2/58, which is on the right of your screen. And 20 ill recruits were tested with the influenza quick test. Nineteen of those individuals were positive.

Now, these two battalions didn't really have any source of common contact. The battalions had separate dining facilities. They trained

separately. And there were no gym or any other common facilities.

Next, please. This is a graph of the ARDs cases, ARDs visits, at Martin Army Community Hospital. And you can see that most visits occurred on April 27th. There were 79 cases reported that day. On the next day, April 28th, there were 48 cases.

Now, these two days completely overwhelmed the capability of Martin Army Community Hospital to the point where sick bays had to be developed in the starship battalion within the most affected unit. And the most affected unit was the 2/58. So sick bays had to be established there.

Next, please. Now, as part of the outbreak investigation, of course, we had to verify the existence of the outbreak. And to do that, we then had to look at rates in the past and compare them to rates presently regarding acute respiratory disease.

With that information, we would then try to develop a case definition. Based upon that, we would then find our cases. And we also, of course, had to find our denominator data, what was the total population at risk. And then during this

whole process, we, of course, were collecting specimens to confirm our diagnosis.

Next. Now, to compare recent rates to past levels of disease, we went through and reviewed ARD surveillance data for the past year. And then we also reviewed previous culture results that had been submitted to Naval Health Research Center in San Diego as part of their emerging disease surveillance.

Based upon that information and once that outbreak had been documented, we were able to devise our case definition. And that was any trainee in the Sand Hill area with a documented oral temperature of greater than or equal to 100.4 and at least one respiratory symptom between the time frame of April 23rd and May 6th, 2000.

Next. Now, in order to find cases, not all of these individuals were hospitalized, even though I did use that term in the previous slide. A lot of them were considered, quote, "on quarters." They were not expected to participate in training. They were in the sick bays.

Some of them were seen as outpatients. So not all of them were hospitalized with complete hospital records. So they were a difficult to

actually find cases. So we had to go through medical record review, unit record review, outpatient records, starship sick bay review.

And then to establish the denominator, we obviously had to look at the entire Sand Hill training area since that's where basic training occurs. And so we've got a population roster for the entire facility, but then we also concentrated primarily on the 2/58 battalion since that seems to be where most of our cases were originating. So we did receive alphabetic rosters for B and D company of 2/58.

Next, please. The physicians on our team along with Sandra Williams collected specimens, such as CBCs. They also collected cultures, throat cultures, both viral and bacterial, as well as serology.

We also then requested services of the industrial hygiene folks at Fort Benning. And they collected data such as CO_2 levels in the barracks while recruits were sleeping. They also measured temperature and humidity levels for us. And they also got information regarding the ventilation system within the barracks itself.

Next, please. Now, in describing the

epidemic, we want to orient the data in terms of time, place, and person. The time was between April 23rd and May 6, 2000, as the previous graph documented. And the place from the Sand Hill area where basic training occurred, the person was a basic trainee with a fever and respiratory symptom. And then we'll just briefly describe the clinical syndrome, too, with a little bit of some laboratory data.

Next, please. This epidemic curve orients the data in terms of time. Normal baseline for ARDs cases is 0.5 ARDs admissions per 100 trainees. And the epidemic or outbreak level is considered 1.5 admissions per 100 trainees. And you can see during our outbreak, we had a level of 2.9, almost sixfold over baseline for ARDs admission rates.

Next, please. This table orients the data by place. We went ahead and looked at all the battalions within the Sand Hill training area. We then had the total population of each battalion, and we compared to the number of trainees that were hospitalized and came up with an attack rate. And the attack rate for the most affected battalion, the 2/58 battalion, was 12.8 percent.

Next, please. Describing the epidemic, we characterized by person. Only male trainees are affected. Because this is infantry training, no females are participants in that. No cadre were ill. It was just the new recruits.

We initially had 194 admissions during the time period, April 23rd to May 6th, 194 admissions. A hundred and twenty-eight of them were from a single unit, the 2/58 unit. And 122 of them were from one company, Company D, of the 2/58. Again, the attack rate for the most affected battalion was 12.8 percent.

Next, please. Again, we had 194 hospitalized individuals between April 23rd and May 6th, but only 107 met our case definition. I'm sorry. I got mixed up last time. And you can see this is just a table describing some of the self-reported symptoms. And they're very typical for individuals with acute respiratory disease.

Next, please. In looking at some laboratory data, we didn't notice any trend towards lymphopenia or thrombocytopenia or cytosis of any type.

Next, please. Now, next we wanted to compare the sick individuals to well individuals

and try and determine who was at risk and why. We did this by performing a case control study. We administered a questionnaire to all members of D company and a random sample of half of individuals within B company. We ended up with 288 participants. Fifty-four were cases, 234 controls, again, all males with a mean age of 20.7 years.

Next, please. And here is the questionnaire, a partial questionnaire, of what we administered to all of the participants. We asked questions about symptoms that they were suffering from. We also asked about their residence prior to coming to Fort Benning. We asked personal hygiene questions, history of smoking, history of asthma, hot water in the barracks, et cetera, things like that.

Next, please. Now, here are some results from the case control study broken down by cases controlled with unadjusted odds ratio. Assignment to D company was associated with case status as well as recent history of smoking with unadjusted odds ratio of 2.2. The fifth week of training was associated. And you'll also notice that there were no cases from barracks that had the ventilation on. Recent smoking is defined as

within the past six months.

Next, please. Here are some results from our univariate analysis. Again, we looked at the variables in the previous table, and we also looked at some other additional variables. You can see that a higher temperature in the bay, greater than 50 trainees per bay associated with case status. White race was, but race overall was not, certainly history of smoking at a younger age.

Now, the two variables that are highlighted in yellow, those were the only two variables that were statistically associated with case status on multi-variate analysis.

Next, please. And the laboratory results. Out of the total population, we only have about 46 acute respiratory patients tested with the influenza quick test. Thirty-one of those were positive.

Now, the viral throat cultures, 47 cultures were obtained on 44 ill recruits. There were three duplicates. Forty-three of those were positive for adenovirus. And among those that were subtyped, the only subtype that was isolated was Subtype 4, Adenovirus Type 4. No influenza was cultured at all from these samples that had been

submitted to the Naval Health Research Center.

Now, the two quick tests that were used initially were the one by Biostar, Flu OIA, and the Kwidel Kwickview Influenza Test.

Next, please. Now, we did do influenza serology. Again, because of the evidence of the quick test being so positive and even though adenovirus grew on most of the cultures, we thought, "Well, maybe there's a co-infection or the adenovirus is overgrowing the influenza." So we wanted to do some influenza serology.

We had hemagglutination inhibition performed at CDC. Paired sera were collected on 40 ill recruits, and the convalescent sera was collected three weeks following the acute collection.

Only one pair of samples demonstrated a fourfold increase in titer between the acute and the convalescent sera. An interesting finding, though, was that most recruits responded very well to the 1999-2000 flu vaccine, as demonstrated by their high level of antibodies against all three components.

Next, please. Now, we had serum neutralization done at WRAIR for adenovirus

antibody detection. Again, same 40 paired sera from the ill recruits were analyzed. And 37 of the 40 paired sera had a fourfold or greater titer from the acute to the convalescent sample. So this laboratory data strongly support the conclusion that Adenovirus Type 4 and not influenza was the etiologic agent.

One of the reasons why the influenza quick tests were erroneous may be due to the fact that they lack specificity for Adenovirus Type 4. Package inserts. Both package inserts state that there is no cross-reactivity with either Adenovirus Type 5 or Adeno Type 7A, but there is no mention about Adenovirus Type 4.

Next, please. Now we would want to discuss how our hypothesis compares to the established fact by reviewing the epidemiologic triad of agent, host, and environment. The agent, of course we were finally able to determine, was Adenovirus Type 4.

That particular subtype is very common within military populations, not very common among civilian populations. Unfortunately, a vaccine is not currently available since all production of this vaccine ceased in 1996, and all stockpile

reserves have been depleted.

As far as the host is concerned, maintaining personal hygiene habits are very important. Also, tobacco cessation can decrease a rate of acute respiratory disease among individuals, but certainly in younger individuals, we're going to see a lack of immunity as well.

Regarding the environment, proper ventilation is absolutely necessary. That includes proper temperature, humidity, proper CO_2 levels. And certainly crowding is an issue. And also you are getting individuals from all over the globe and basically putting them into the in-processing area and then assigning them to units.

Next, please. Now, although some control measures cannot be altered, such as the availability of a vaccine, some measures can be implemented, to minimize the risk of acute respiratory disease in military settings.

One of those is maintaining the proper operation of the ventilation system. That includes regular cleaning of the vents, timely replacement of the filters, making sure that they're on when they're supposed to be.

And another way that we can control ARDs

is to emphasize NOVARDI, which are non-vaccine acute respiratory disease interventions. And that consists of personal hygiene measures, such as washing of the hands with soap on a regular basis, providing adequate space per recruit of 72 square feet as per Army regs. Also head-to-toe bunk orientation may help minimize aerosol transmission of pathogens.

And then certainly surveillance is very important to maintain the weekly surveillance of acute respiratory disease cases to see if you're getting a little bit of an increase or a spike.

Certainly pathogen sampling among hospitalized ARDs cases is also very important, especially if you need to go back and compare rates of last year to rates of this year.

Now, since there didn't seem to be a problem with initially we were concerned that the problem was influenza. We were worried that maybe the vaccine wasn't effective. But since it turned out to be adenovirus and not an issue with influenza, we also recommend to continue in processing the way it has been going on since that didn't seem to be a real concern.

Next, please. And there are some

acknowledgements that I would like to point out. We had a lot of help from individuals at Fort Benning. And certainly for their laboratory support, we couldn't have done this without the folks at Naval Health Research Center, WRAIR, and CDC.

That's all I have for the outbreak. Are there any questions? Yes?

PRESIDING OFFICER LaFORCE: Lots.

DR. DuVERNOY: I'm sorry. Okay.

PRESIDING OFFICER LaFORCE: Go.

DISCUSSION

CDR LUDWIG: Dr. Ludwig here. I'm curious about on your discussion slide, you talk about tobacco cessation can decrease the rate of ARDs. As I remember, these trainees are non-smoking during training anyway; right?

DR. DuVERNOY: Theoretically.

(Laughter.)

CDR LUDWIG: I think that's probably true because they're pretty well-controlled, but I'm wondering. It seems like your association is with a history of smoking; right? It was with onset of smoking earlier than 20 years old. Is that right?

DR. DuVERNOY: No. Within the past six months.

CDR LUDWIG: But since they theoretically are not smoking during basic training, we're not sure whether ceasing smoking could decrease the rate of ARD.

PRESIDING OFFICER LaFORCE: Other questions? Yes? Who have we got? Steve?

DR. OSTROFF: I have a couple of questions. Steve Ostroff from CDC.

DR. DuVERNOY: Okay.

DR. OSTROFF: First, I wonder if you can give us some sense of what the overall impact of the outbreak was in terms of how long people remained hospitalized, what the impact was on their training, and issues like that, number one.

DR. DuVERNOY: Okay. Actually, the average length of stay or out of training was 2.6 days. And, actually, that may certainly add up, especially when you're talking about a very confined time period to get all of this training in. But, actually, all trainees completed their training on time and graduated on time.

So it didn't impact them in the long run, but certainly everybody was worried while they

were ill and weren't able to be practicing.

DR. OSTROFF: The second is, I mean, it's a really amazing epicurve to see something that's that explosive. I mean, basically it all happened over a period of 48 hours, essentially. It's pretty unusual.

DR. DuVERNOY: Right.

DR. OSTROFF: What do you think really happened? You know, you talked about 50 trainees per bay. Was this basically all in one or two barracks or --

DR. DuVERNOY: It seemed to occur that way. What we suspect happened was maybe there was some cohorting effect going on and everybody within Company D got sick.

DR. OSTROFF: Did you actually plot it by barracks and look at where their folks were in relation to other --

DR. DuVERNOY: We weren't able to get that information, but based on who was ill and wasn't ill, this is what we surmised.

DR. OSTROFF: And the third question I have is I'm curious about not having soap in the barracks. Is that --

DR. DuVERNOY: Oh, we were pretty

amazed. Some people didn't know that there was even soap there. On the questionnaire, we have "Yes," "No," "Don't know." Is there soap in the barracks? Don't know.

And also some people didn't know if there was hot water available. So we were rather surprised by some of the response. We entered it as they gave it to us. So it was interesting.

PRESIDING OFFICER LaFORCE: Ken?

CAPT SCHOR: Ken Schor.

With regard to hand-washing, actually, at Parris Island, there almost is not enough time for the recruits to actually run through and wash their hands before they eat because their schedule is so intense for ten weeks.

They got around that by actually buying the alcohol-based hand cleaners and making it Marine-proof by putting it in a gallon ketchup container in a stainless steel cage so they couldn't eat it or something. I'm not quite sure.

(Laughter.)

CAPT SCHOR: I'd like to mention that to Commander Ludwig also. They instituted that about a year and a half ago. And I guess we'll have to see what the impact of that is.

The intensity of these training scenarios is pretty amazing. And the folks are just so tired and their days are just so long that they want to just be -- and washing hands is very secondary to eating at that point.

PRESIDING OFFICER LaFORCE: Yes?

COL SMITH: Dr. Paul Smith.

I have one question. Do you have any idea of what part of the training cycle these people were in when this outbreak occurred?

DR. DuVERNOY: I'm sorry? What part of what?

COL SMITH: What part of the training cycle? Were they in week one, week two, week three, week four?

DR. DuVERNOY: Primarily week five.

COL SMITH: So they were about mid-training cycle, give or take. Thanks.

DR. DuVERNOY: Although we did have some cases for individuals who were in week four and week six but primarily week five.

Yes?

DR. BERG: Bill Berg.

I have two questions. You said they were hospitalized for an average of about 2.6 days?

DR. DuVERNOY: Well, actually, I guess I shouldn't say "hospitalized." They were out of commission, so to speak. They were on quarters.

DR. BERG: Okay. How long did it take for them before they could get back to their full schedule of physical fitness training, particularly running?

DR. DuVERNOY: We didn't ask that. We weren't following up with that. But we did ask at the very end if anybody was unable to complete their training in a specified time. And we were told that everyone graduated on time.

DR. BERG: My second question is: Could you elaborate a little bit on how cleaning the ventilation systems and the filters would work to diminish outbreaks like this? These aren't HEPA filters, are they?

DR. DuVERNOY: I believe they are. No? Okay. Okay. Regular filters.

DR. BERG: I mean, I can see if they're grossly dirty and there's a lot of particles in the air maybe irritating things, but beyond that, I'm not sure how much the --

DR. DuVERNOY: Well, certainly having a working ventilation system would be helpful.

Obviously there is a certain amount of air exchange that needs to occur. And when the filters are clogged, then you may not be getting that exchange rate at all. So then you just have stagnant air.

So I think that's the main issue as far as maintaining the ventilation systems properly to make sure that you have that minimum exchange of air occurring.

PRESIDING OFFICER LaFORCE: Pierce?

COL GARDNER: Pierce Gardner.

This is another interesting study correlating the smoking risk with infection in the last year, there's been a rather elegant study in pneumococcal, the base of pneumococcal disease, identifying smoking as the single most important risk factor, ahead of all the other things we have traditionally done in people between age 18 and 64. There has been some indication that influenza risk has also increased and now adenovirus. So that's important.

In the pneumococcal study, they did a nice job in the dose-response curve. The more smoking, the higher the risk. And if you stop smoking, you go back to -- did you have any data that could correlate degree, how much smoking,

versus how much risk?

DR. DuVERNOY: Well, initially on the questionnaire, we asked if they had ever smoked. And then we had one category where it was less than or equal to a pack a day and then greater than a pack a day. So we really didn't break it down any more than that.

COL GARDNER: Greater than a pack a day, more than or less than a pack a day?

DR. DuVERNOY: Actually, we didn't see that, no.

COL GARDNER: Okay.

DR. DuVERNOY: Just smoking in general we --

COL GARDNER: I think the Board in terms of readiness in younger age groups, this becomes increasingly evident that smoking cessation probably relates to preparedness and susceptibility.

PRESIDING OFFICER LaFORCE: Thank you.

DR. BERG: Last question. Bill Berg.

Did anyone get back to the manufacturer about why they omitted to eliminate the cross-reaction with Adenovirus Type 4?

DR. DuVERNOY: Actually, no one has

contacted the company, but I'm assuming it's because Adenovirus Type 4 just isn't common within civilian populations. It's primarily military issues.

So I guess it probably wasn't worth it to spend that amount of money to try and get lack of cross-reactivity with Adeno 4 since it's such a small population at that risk.

PRESIDING OFFICER LaFORCE: I think this is an important lesson for other military facilities. I think it is a very important lesson.

DR. DuVERNOY: Don't use influenza quick tests.

Captain Gray, did you want to add something? I cut you off. I'm sorry.

PRESIDING OFFICER LaFORCE: Okay?

DR. DuVERNOY: All right. Thanks.

PRESIDING OFFICER LaFORCE: Let's move on to Captain Gray, Lieutenant Colonel Neville on morbidity and other losses associated with failure of adenovirus virus vaccine. It's a pretty thick handout I think that goes along with the presentation.

MORBIDITY & OTHER LOSSES ASSOCIATED WITH THE FAILURE OF ADENOVIRUS VACCINE

CAPT GRAY: Yes. Hi. I'm Greg Gray from the Naval Health Research Center. And Joel has given you the handout here. I want to make sure you take this with you because he worked really hard to compile these articles. Also, there's a handout with my presentation on it that you should have.

With respect to the last question, the reason that the two rapid tests were on site is that our laboratory was evaluating them to determine if they were useful to the military. The bottom line is the pharmaceutical companies now have adenovirus 4 wild type, and they're evaluating their product with that in mind to see if they can replicate.

Of course, there are charges that our technicians, although trained by their reps, perhaps didn't read the tests right, too. So we're wrestling with those issues.

I probably don't have to remind this Board that we have a national decline in public health laboratory capabilities. And the Department of Defense is certainly a component of that.

What I'm going to tell you today is pieced together from recent efforts to reestablish

some of those capabilities in the Department of Defense, particularly targeting towards adenovirus, but by no means is it a comprehensive look at the impact. Instead, what we have are some small studies examining the prevalence of various different adenovirus serotypes.

Next slide. Just to review, adenovirus has been a leading cause of febrile respiratory illness in trainees, particularly before the vaccines were developed, by the predecessors of the folks in the commissions, in this Board right here in this room.

It was found to be the oral attenuated products after a number of different attempts through killed viruses that are well-recorded in Dr. Gaydos' article, was found to be very effective and employed from 1971 to 1996. We really didn't have a big adenovirus problem until just recently.

In 1996 -- and the story is rather complicated, but the manufacturer decided for economic reasons to stop production. We had limited stores available 1970 to 1999. And all our vaccine after -- we basically tried to use it just in the winter months to save it. All our vaccine was depleted in the early part of 1999.

Next slide. With very modest funds, largely through the champion of Captain Trump at BUMED, Bureau of Medicine and Surgery, we established a small adenovirus capability in San Diego. The focus was to determine if the serotypes that were most prevalent 20 years ago were still around and if the vaccine still seemed to be working during the time frame where we're going to start losing the vaccine.

Next slide. We established surveillance. This is active surveillance with research assistants on board governing the collection at five sites, four of which were viable and shown here: MCRP San Diego; Fort Jackson, South Carolina; Fort Leonard Wood, Missouri; and Recruit Training Center in Great Lakes, Illinois.

Next slide. In this active surveillance system, we have monitored for febrile respiratory illness infection rates, collecting both numerator and denominator data. And whenever we had a trainee that came during the normal working hours with the case definition you see here, we asked them to permit us to collect a throat swab for viral culture, which was preserved at -70 and shipped in batch to our facility.

We used A549 cell culture techniques. Dr. Snur at the California State Laboratory transferred microneutralization typing technology to us, and we used his typing technique.

Next slide. Overall, -- and we're just going to try to summarize our findings, but we had a remarkable isolation percentage considering all of the coal chain issues and the handling problems that are fraught at our MTS. Fifty-three percent of 3,400 specimens were adenovirus-positive.

Next slide. And this is in the time period where we were rationing vaccines. So sometimes we're using it. Sometimes we're not. You can see that in winter months, -- and this is historically true -- there is a variation in adenovirus vaccine or adenovirus wild-type infections, with the winter months always being high. You can see that in some cases we've got, almost 90-100 percent of the viral cultures submitted to us were positive for adenovirus.

Next slide. In the aggregate, we isolated Types 4 and 7, which are historically the most prevalent types. So nothing had really changed with respect to that. We also had Type 21, for which there was a vaccine in the test phases

but never produced. We did have a significant number of Type 3's.

Next slide. You can see that the distribution of the serotypes varied with the various different MTFs. Remarkably, we had an outbreak here of 3 and 7, which really doesn't happen very often. At least it hasn't happened much in the literature.

The most prevalent serotypes at the other sites was Type 4. Incidentally, at the emerging infectious disease conference, just about a couple of months ago, the CDC had received some of our specimens and through restriction enzyme analysis showed that this particular strain of seven was identical to the strains that had caused pediatric outbreaks in the Chicago area, also pediatric outbreaks with death.

So there is some possibility that perhaps we had a more virulent strain here. I'll say now and I'll show you in a minute that this is now regress. There is no 3 this year at all. It's all 4 -- next slide -- or no 3 or 7. It's almost all 4.

You can see that if you received the vaccine, you were really protected among the throat

cultures we got that met the case definition. And if you did have a positive throat culture, it's a good chance it was 21. If you did not receive the vaccines, again, 4 and 7 were most prevalent.

Next slide. The odds ratio for having a positive culture among our cases was 13 times that for those who had not received the vaccine as compared to people that had been vaccinated.

If you look at the specific, either a 4 or a 7, 28 times the odds. So it looked like to us epidemiologically that there still seemed to be a protective effect, although these are sort of indirect data. The vaccines still seemed to be appropriate for the wild-type viruses that were out there.

Next slide. In June 1998, -- and I must say that the initial funding from Bureau of Medicine and Surgery was supplemented with global emerging infectious disease surveillance funding from DOD Health Affairs managed by the central hub here.

And shortly thereafter, we were encouraged to expand our effort and to marry it with Project GARGLE. You hear a little bit about Project GARGLE perhaps at other meetings.

The idea at Project GARGLE is largely a flu surveillance since we wanted to broaden this and look for other viral pathogens and also add some other sites. Next slide. And we followed this regimen since that time.

We added three more sites: MCRD Parris Island, Fort Benning, and Cape May, which you heard a little bit about this morning. We also had Fort Bragg for a time, but basically it didn't have enough cultures to keep us interested in keeping a research assistant there.

Next slide. We changed the methodology a little bit in that we just couldn't maintain the high volume of culturing when we added these additional sites. So we reduced it to a systematic sample with a sliding scale so that we don't culture every isolate or every patient, we only culture a proportion of those. And we changed the case definition just a little bit to be more consistent with Project GARGLE.

We now culture for influenza A and B, respiratory syncytial virus, and the parainfluenzas. And we do adenovirus and influenza typing with CDC typing sera.

Next slide. Here you see results from

the 4,300 specimens collected since June of '98. And you can see again adenovirus is the most common isolate, but we do have flu A, flu B, and a number of other viruses.

Next slide. The proportional distribution of cases -- I changed the order a little bit in your handout, but the proportional distribution of the cases differed with sites, with most of the training facilities having adenovirus as the most prevalent virus, but Fort Bragg, a post-training site, having this one facility, Fort Bragg, having a higher prevalence of flu A.

I think this suggests that flu A is perhaps not being used as much in the higher proportion of people and that's why we see this problem, and perhaps these people are not berthed in as crowded areas as the trainees are.

Next slide. These are our febrile respiratory illness rates. They're updated weekly on our worldwide Web site. We tried to give feedback to all the folks participating. And you can see that we have exceeded the threshold for a number of different sites over time, the threshold of 1.5 cases per trainee per week that's been historically the FRI threshold.

There are a lot of things that people have considered and a lot of recommendations, but I just think we're going to have these outbreaks for a long time until we get the vaccine back.

Next slide. This perhaps is the best slide we have towards the theme of the title of the talk. And that is: What is the clinical impact of these adenovirus outbreaks?

This is an aggregate slide where we take the febrile respiratory illness rate. We determine the proportion of the samples we received, the proportion that were adenovirus-positive. And we extrapolate the number of cases that we think we had at that site based on these data.

You can see for the month of October 1999 that we had nearly 2,000 vaccine-preventible clinical encounters, many of whom were hospitalized or set under some supervisory care. It's just remarkable the morbidity that we're going to be faced with, particularly every winter, from the loss of these vaccines.

Next slide. This is a slide to show you the temporal effect. I think Sharon had a pretty good one as well. When we had vaccine available, we just didn't have these problems. When we

started rationing vaccine, we would have an increase. And then we would slap it with vaccine, and it would go down and it would go up, et cetera. So there's just going to be this vacillating, I think, of the FRI rates. Largely, it's due to adenovirus infections.

Next slide. Some of the things that have been done recently -- and you have a number of these papers in your packet in emerging infectious diseases. The first outbreak among female Army trainees that had ever occurred and was well-documented there, at Fort Gordon in a recent publication, the same journal, we demonstrated the transmission or colleagues demonstrated the transmission from Fort Jackson, a recruit training facility, to Fort Gordon, another advanced training facility, where 50 percent of 147 hospitalized trainees were infected.

We have a paper that is in the works, "The Outbreak of Adenovirus 3 and 7," which, interestingly, shows a protective effect for a history of smoking. So I think that's somewhat to be debated: the smoking interventions.

Then, of course, you're going to hear a lot about the outbreak at Lackland here in just a

minute from Dr. Neville. And, then, finally, there's been the Fort Benning outbreak you heard about earlier.

Next slide. These are the same data, again, just to show you the explosiveness of the Cape May outbreak.

Next slide. You might ask: Well, what kind of serious morbidity? It's not really a reportable disease. So we don't have a good handle on this. But anecdotally we have heard of the glomerulonephritis case, thyroid storm case with adenovirus implicated, and at least two admissions in the intensive care unit at Great Lakes.

I think what is really concerning to me are the three articles in the literature in your handout there of mortality cases. I just anticipate with this volume of cases we're going to get to mortality cases eventually. And there is going to be a lot of finger-pointing at folks because of that.

Next slide. With respect to hospital impact, you have heard a little bit about this, but basically some of the hospitals have had to shut down their facilities and open up other facilities just to take care of these people.

At Fort Benning, they had to shut down the post-op area, cancel elective surgeries. Lackland has estimated their costs from their recent outbreaks at three million dollars. Fort Leonard Wood had to open a special infirmary ward to take care of them. Cape May said their hospital census went up fourfold.

Next slide. Lackland, although some places say they have not had a problem with recycling, other places say they have had a problem with recycling. And that is delayed graduation of the trainees, where they have to be sent back to earlier classes.

Lackland reports a 20-fold increase. Great Lakes, the training commander got so upset, he called the hospital commander and demanded that this be ended and that we get the vaccine back. Recycling increases were noted at the other sites. Cape May even discharged one of the admissions. I'm not really sure about that. Basically it was severe enough.

Next slide. Well, you might be saying: Well, what are we doing besides just watching this happen? You know, it's rather frustrating.

I should tell you that a lot of things

have been considered. We have talked about reducing the crowding. We have talked about washing hands. There was some talk about hand-washing with antimicrobial little hand wipes. There are some data that were done some years ago about UV light filters. We have a paper in the works on that but not much protection shown.

And, of course, we think a lot of this is person to person; whereas, ventilation might help. Really, we're just going to be faced with this for a long time as long as we do business the way we have in training recruits.

So we're trying to figure out considering now that we have a problem not only with adenovirus but also with influenza. How are we going to tell quickly which is it? And you know about the confounding rapid tests of the influenza.

Well, there is an off-the-shelf adenovirus rapid test. We have evaluated it briefly in collaboration with the manufacturer, SA Scientific. Frankly, the sensitivity is not real good, about 40 percent, specificity about 90 percent, with rather tight confidence intervals. So while it might tell us of an outbreak if we get a lot of positive tests, it's not going to help us

to discern some confusing data.

Next slide. We have been in collaboration with the state, California State Lab, where they do have a very nice adenovirus program for many years and also the CDC. And we developed restriction enzyme analyses capabilities and most recently DNA sequencing capabilities to try to distinguish the strains and determine if we can ever identify most virulent strains if we have got one of those in our populations.

I mentioned that the CDC had some indications that seven had changed recently. In fact, we found a very unusual strain, only thought to be seen in South America. We found one case among an ill trainee in Lackland.

But there is some work nationally to try to get a better handle on adenovirus in the various different genotypes and serotypes and figure out what we can do about it.

Next slide. There have been some efficacy studies, one of which you have by Dr. Howell. Looking at the data in this fashion, a very sophisticated one, it looks like without the vaccines, we have projected 12,000 in the Army alone adenovirus hospitalizations would occur

annually. This is with the old policy of admitting every one at a cost of 26.4 annually million. Then year-round vaccination would prevent 7,800 admissions and save $15.5 million annually. This again is just in the Army alone.

There is another paper that is in press. I've forgotten the journal. I'm sorry. But it will show similar estimations very much in favor of returning the vaccine for the Navy and Marine Corps personnel.

Next slide. Well, I don't mean to bash Charlie Hoke back there, but what we have here is a situation where we had a lot of public health efforts regarding domestic problems in the DOD.

And over the years, those sort of waned and we focused on operational type programs, the hemorrhagic fevers, malaria, rickettsia, diseases that are not often endemic and not often evaluated by the UH.SE. Public Health Service. And so the idea was to put our money where we had all of these problems that were operationally important and were essentially neglected.

I think I would like to make a case and ask the Board to weigh in on it that we do have a lot of respiratory illness. And while there is a

lot of domestic effort, certainly adenovirus isn't getting a lot of national funding, adenovirus vaccines.

And if you guess that many of the different hospitalizations we show here using the aggregate of ICD-9 codes are due to adenovirus, then you could see that we could greatly reduce those admissions. Anyway, I think it merits some consideration.

I know there have been $15 million moved this fiscal year to get a start-up towards the vaccine. Perhaps there are some folks in the room who could talk about that, but it seems an appropriate area to focus some of our R&D efforts.

Next slide. And, finally, through this modest effort through the Global Emerging Infectious Disease program, we now do have a modest laboratory capability to handle these outbreaks. And coupled with sort of the basic science research that's here in this institution, we're able to provide some support.

It's very tenable, and it depends on year-to-year funding. It may very well go away after a few years unless we do something to make it more of an established institution. In fact, there

are about 20 people working in this, not all of the people in this group.

That's all I have. I'd be happy to take any questions? And we'll let -- Jim Neville up here real quick.

PRESIDING OFFICER LaFORCE: I think we're going to hold the questions and then go right on to Lieutenant Colonel Neville's presentation. And then after that, we'll do the whole questions together.

LTC NEVILLE: I feel honored to be here. I'm Lieutenant Colonel Neville, preventive medicine doc at Brooks Air Force Base, which is shorter than saying, the full-cell protection is surveillance branch of the Air Force and student environment, safety, and occupational health risk analysis. So Brooks is better.

I'm just going to present a brief overview of the situation at Lackland Air Force Base over the last nine months, not a whole lot of detail unless there are questions about that.

Next slide, please. Lackland Air Force Base is the only basic training site for the Air Force. And as well as the basic training, there are eight different schools, technical schools or

other schools, at Lackland Air Force Base, tri-service or Air Force alone.

That includes Defense Language Institute, which trains foreign nationals mostly in English when it's military. And there's a Pan-American Air Academy for mostly Central and South American Air Forces that come here.

So there's a whole mix of people at Lackland Air Force Base. This focus is just on the basic trainees, though, not all of these other populations. This should say 3,500 to 6,000 basic trainees at any one time at Lackland Air Force Base.

Six hundred to 1,100 arrive every week 50 weeks out of the year. And in the summer months, there's a slide here in a second that will show the number of recruits that arrive that are at Lackland being trained increases.

The organization is that there are six basic training squadrons. Within each of those squadrons, there are 10 to 12 usually but when it's crowded up to 20 flights per squadron. There are usually 50 to 60 trainees in each of those flights. The basic training period is six weeks. In the other services, I think it's eight weeks.

Next slide. Like any military place, training place, this is crowded. This is a classroom setting. And you can see how these desks are spaced as close as they can be. They touch. They go from wall to wall, to narrow aisle, down the middle for the instructor to walk around, make sure everyone is staying awake. You can barely see, but in the back, that's a row full of people, too. So this classroom is real crowded.

This is a day room adjacent to the sleeping areas. They do some mail call administrative training and so on in the evenings here. Sometimes there are two flights in this room. So maybe 120 guys sitting on this, recruits, trainees, I should say, sitting on this floor getting some kind of training going on. So it's crowded in there, too.

This is the sleeping area. You can't really see on this thing, but that's a pillow. There's a pillow, pillow. So they're head to foot, head to foot. It's not quite as crowded here as it is in the classroom setting.

Next slide. And this just shows the weekly census, if you will, of trainees at Lackland. In June, it goes up to about 6,000

trainees at Lackland, even as we speak here. And that's about their capacity. So all of those barracks places, all of those sleeping areas are full.

Next slide. Now, if we went back in time -- my office got called to try to see what else could be done around April. It's kind of hard to tell where that is. That's somewhere around in here.

Lackland Air Force Base has a medical center, Wilford Hall Medical Center. They have infectious disease, public health, and all of this kind of stuff. They were certainly trying to do what they could do, but our offices were asked to see what else could be done.

Anyway, when we look back in time, this is the ambulatory coding from the troop clinics. So when people, the basic trainees, just limited to basic trainees, show up at their sick call, they get discharged with some kind of a respiratory code.

This is the codes for all respiratory illnesses, not necessarily adenovirus. We were trying to establish the existence of an outbreak, like we've heard about already.

Anyway, this is pretty low. And it seemed kind of obvious that there is a dramatic rise in respiratory cases being seen at sick call. The inpatient ward was opened on the 24th of November in response to this dramatic increase.

Next slide. Now, this is a seven-day moving average of daily admissions to Wilford Hall for febrile respiratory illness, acute febrile respiratory illness. So the ward was opened on the 24th of November. Seven days after, you can get a seven-day average.

This is the number of admissions. So every day, here it was five to six or whatever. April and May went up to 15-17 admissions a day at the peak and then kind of waned down a little bit.

Only two points on here I put on this slide -- well, three, I guess, for that one, but the policy was changed to admit every recruit that had a fever who came to sick call.

And then the policy, maybe because of the overflow, -- I'm not sure -- was changed to admit just by the provider's discretion if there was a fever. So if a guy had just a little bit of a fever and he wasn't that sick, then he didn't have to be admitted.

This little thing is a cost estimate slide I'll show in just a few minutes, but this is the time period that I'll use for that estimate, not the peak; this one, more recent.

Okay. Next slide. This is very similar information, but it's the rate, hospitalization rates, per 1,000 trainees. Some of this stuff that I'm presenting, we're already talked about a little bit here.

What's interesting also is that periodicity that was mentioned before, every three to five weeks or so, there's a peak. And it goes almost all the way through.

The next slide. I should have pointed out that that rate is ongoing. It doesn't drop to zero. It's still ongoing. So even last week, there was an average of seven admissions a day.

We reviewed 352 of the inpatient records. The only point of this slide is to demonstrate that these people are relatively sick. They don't just have a cold. Mean and median, as it turns out, max. temp. recorded on the chart was 102.3. And this is their distribution of symptoms that they reported in the record.

Twenty-five percent of the people who

had chest X-rays done had some abnormality. And 40 percent of the total of the inpatient records that were reviewed had some indication in the medical record of some level of dehydration.

Okay. The next slide. Now, in terms of the cost, it's kind of a hard thing to get an exact cost number, but these are estimates. So for that 31-day period that's recent -- it's not the peak of all of those admissions, but the recent 31-day period that was on that other slide, there were 163 hospitalizations of trainees.

I'm told that an inpatient internal medicine bed day costs $1,340 total cost. There's a 2.7-day length of stay, which was not much different than we heard before.

So if you multiply it out, that's $589,000 about. That does not include the displaced hospital inpatient capacity that Captain Gray just mentioned.

So that if this war gets overfilled, those trainees go to the pediatrics ward or the orthopedic ward or whatever. And then those beds aren't available for the pediatrics cases in the ER or whatever it is.

That relates to the GME training

opportunities. If there's a recruit in the bed, then the kid with the meningitis can't come in and the resident can't get the meningitis case and so on. This doesn't account for any of those kinds of things.

The lost professional staff, in the first maybe six months of this stuff, they had to have a staff guy staffing the ward for the residents so that the pediatric cardiologist or the urologist or whoever would take his turn on staffing that ward. So obviously he couldn't be in the clinic seeing their patients and so on. So this doesn't account for any of those kinds of things.

The line commanders tell us that they estimate a cost of a lost training day for basic training at $110, whatever that means. If there are 163 hospitalizations and they lost 3 days, then that comes to that. So if you take both of those numbers together, -- can you hit "Advance" three more times or maybe four -- it's about $20,000 a day during this time period.

Okay. Next slide. Captain Gray mentioned this, too. This is just the graphic of it. This is recycles. Does everybody understand

what recycle is? Shall I explain that one more time? That's okay? Does everybody understand? Okay.

So last year or Fiscal Year '99, a cumulative total here was like eight I think or nine for the whole year. For Fiscal Year '00, the cumulative total is here, 122. So that's 24 times the number of medical recycles.

Now, this includes anything medical. So it's not just adenovirus-related, but there's no evidence of any other outbreaks of orthopedic injuries or surgeries or whatever else.

This is important to a certain extent because when the trainee gets recycled back to another training time, he misses his graduation date or he misses that technical start date. And that may put that person back a couple or six months maybe in their training cycle or they have to do a different job or whatever. And it's a big headache for the trainers and the recruits, too, certainly.

Okay. Next slide.

COL DINIEGA: Do you know what the denominator is?

LTC NEVILLE: That's just counts.

COL DINIEGA: But, I mean, what's the total people that went through training during that period in --

LTC NEVILLE: It's probably large.

COL DINIEGA: So you have a small --

LTC NEVILLE: Probably 35,000 in a year get training. That's an estimate. Okay. So on the 7th of May on a Sunday afternoon, we went and cultured everybody walking into the fifth week of training as warrior week, which is a field training sort of a week, rather intense and so on.

So they're carrying their packs and shuffling in through the tents. So they're relatively healthy. They're not sick or whatever. So we cultured all of those people. And of the 386 cultures, 64 of them were positive for adenovirus. Scratch out that. This is the final thing, not an intermediate thing.

We asked them if they had any symptoms, respiratory symptoms, and looked real quick if they had respiratory symptoms. It had nothing to do with whether they were positive or not.

Incidentally, of this cohort of 386 people, 53 of them either had been admitted during their training or subsequently would be admitted

during their training. So 13 percent of that cohort had been admitted.

Okay. Next slide. This is indoor air quality. If the ASHRI standard is 1,000 parts per million CO_2 in an indoor environment, this measurement is a reproduction of the tracing from this classroom setting. It goes way above that and stays up there when they're in the classroom.

This is about a two-hour period, two or three-hour period. Where they sleep, we measure this in maybe four different sleeping areas. And it never got over 1,000. It was 900 or so but never got over 1,000 during the night. So my own feeling is that the classroom is the worst place for indoor air quality.

Okay. Next slide. Now, when we recommended the interventions -- I'll just go through this real briefly because we've already talked about some of those things.

Most of these things aren't proven for adenovirus. Vaccine is certainly -- and maybe I shouldn't say crowding is proven for adenovirus either, but it is probably more proven than the others.

These are the recommendations that we

said to the hospital command and to the line commanders that they ought to do. There's a list of detail of these. I didn't reproduce that.

We asked for the line commanders and the hospital command to send letters up to abrogate for the vaccine. We recommended certain things, how to decrease the crowding, but that's probably a waste of time because the crowding is more of a problem now. We recommend the hand-washing when they can and so on.

Indoor air quality, trying to make some intervention there, although it's difficult in that classroom setting because the air design is such that there is no fresh air coming in. It circulates indoor air over heating and cooling coils. So there's no fresh air designed to come into those places. Ongoing surveillance and the rest of that.

Okay. Go to the next slide. Just the last part of August, we went over there just to take a quick snapshot picture of what these things had been doing. The line commander said they had done most of that stuff.

The letter from the line side is on its way to the two-star aiming for the four-star there,

Education and Training Command, the line side. Whether it goes that far and where it goes from there, who knows. The SG, the hospital commander sign that letter. So they're supposed to be going together along the command chain.

The crowding I mentioned isn't any better, although they have spaced the recruits apart a little bit, like when they are in a line going into the chow hall, they're supposed to be heel to toe right next to each other. On the questionnaires, we asked them. They said: Yes. If the guy doesn't sneeze on the back of my neck, maybe I won't get sick. So they space them out maybe a foot or two now. That's maybe one benefit.

The same we heard a minute ago about hand-washing. The sinks. They actually have about nine sinks in their dorm area. They turned the water off to seven of them so they don't have to clean them. So all of the water is on now, but they still looked pretty dry when I looked at them. They say it's easier to wash their hands before they eat and so on.

Indoor air quality. Nothing is happening. Ongoing surveillance. It's a more difficult thing to do the surveillance for the

ambulatory febrile respiratory cases. It's easier to do the inpatient cases. But that's improving now. The NHRC has funded a research assistant position there at Lackland to facilitate gathering that ambulatory data. And the rest of this is kind of weak recommendations anyway.

I think that's probably it. The next slide. So that's where we are.

PRESIDING OFFICER LaFORCE: Okay.

LTC NEVILLE: Okay. Any questions?

PRESIDING OFFICER LaFORCE: Let's open this up for questions for the last two presentations for the next ten minutes or so, if you would, please. Colonel Smith?

DISCUSSION

COL SMITH: Up until recently, I understand that the Air Force had no problems with adenovirus. And I think that that's somewhat a true statement. And you have not used the vaccine?

LTC NEVILLE: Since '87 we haven't used the vaccine.

COL SMITH: And suddenly you're having outbreaks of adenovirus?

LTC NEVILLE: Right.

COL SMITH: Do you have any inkling of

what has changed? The agent? Host? The environment? Something has changed.

LTC NEVILLE: Something has changed. And that's a good question. I don't have any evidence to say one way or the other. Some people think that because the other services haven't had vaccine as well. And Lackland is a place where other services feed trainees to: the Defense Language Institute, for example. Maybe we're getting more adenovirus from other places and it's the Army's fault. Nobody knows why that's the case.

Now, I will say in the Project GARGLE, we have had isolated, maybe one or two in a month isolates of adenovirus, at Lackland, maybe sometimes five to ten from Shephard, which is the main technical school in the Air Force, but never any outbreak like this one. But I don't know why it's happening.

PRESIDING OFFICER LaFORCE: Yes, sir?

COL DINIEGA: Jim, nice presentation for all three of the speakers who spoke on the ARD. It comes across very clearly that what we have as far as impacts go is very little impact on recycling or on the line side of the house and a large impact on

the medical side of the house.

So I would not be surprised if it defined -- support for the vaccine from the line side of the house may be a little harder to get. I know it's already tough to get it from the medical side of the house.

But the other question I had is: There's been I think an area we haven't looked at. And that's ARDs during deployment or FRIs during deployments. It's a very tough one to put your finger on. But I think deployment FRIs will probably lend to getting more support. I know on most of the deployment surveillances, ARD is one of the leading causes of morbidity.

Next to me is Dr. Hoke. Dr. Hoke was in charge of the money, $12 million, that was given from Health Affairs. So I'm sure people want to hear about what he has to say.

DR. HOKE: I do want to speak, but I need to parse my words very carefully. We all had a lot to do with getting that money. Many, many people in the room contributed in what was an e-mail campaign several years ago to identify funds for reestablishing an adenovirus capability.

That money, about 14 million, eventually

did come down to Medical Research and Materiel Command, to General Parker. Mr. Bill Howell, his deputy for acquisitions, is responsible for that effort. It's not a part of the Military Infectious Disease Research Program, which I direct.

So that effort is ongoing and progressing, although perhaps not as quickly as we might like. Many visits to the former manufacturer have taken place. The production methods have been all abstracted and are now ready for the potential follow-on manufacturer to use in formulating their proposal. And the request for proposals will be issued shortly. So there is clear progress.

I will say that, in addition, we did include from our Infectious Diseases Program this adenovirus issue as one of our top important issues in the POM process, which is how we get funding in five-year sort of chunks in the last iteration of that process. And our request for additional funding for those items was not granted.

That is getting up to the influence of the chief of staff of the Army and I think reflects many factors, but one important factor in a general sense is that the line side of the Army is not feeling the pain, is not feeling that -- this

hasn't risen to their screen. Of course, they're thinking about millions of things.

I was very encouraged about your comments on the letter that was going up through Air Force channels because back when we were trying to get this original money, the Air Force were calling it like they saw it.

They had no problem. That's what they said. That swayed Dr. Bailey to basically recommend very temporizing measures about the changing facilities and so forth and not to support, at least initially, the vaccine redevelopment effort.

I was talking to Dr. Miller the other day. And it appears that the Army TRADOC surgeon is completely unaware of this issue: the lack of adenovirus vaccine or the impact of adenovirus on training populations.

So I think we need to enter a phase of trying to figure out how to educate the line that they want this because it is really the line that does control or has a huge influence on what dollars are made available.

You know, addressing Captain Gray's very compelling slide -- I don't have it here in front

of me, but it was so memorable that I don't think I need to look at it again, the one with the figures, with the dollars spent per disease case and so forth.

I certainly appreciate the thrust and motivation and emphasis there, but it is clear that the Military Infectious Diseases Research Program does direct its efforts at diseases of deployment, diseases that are likely to be encountered abroad, and which are likely to affect the outcome of the military operation.

So while those figures may suggest a rather disproportionate amount of funding for some of those things, they do seem to be the ones that would most likely affect military operations.

This adenovirus issue has peculiarities in terms of the acquisition system that make it difficult. To be truthful, from a basic science, from a vaccine development point of view, we don't have to do anything.

That's not the issue. We don't have to discover the vaccine. So whenever I've raised the issue, I'm kind of put down, not in a rough sense, but I'm told that, "Well, what discovery do you need to do on the product?" We don't have to do

anything. We just have to identify a manufacturer.

So I know that I sound a little defensive, and probably I am being a little defensive. But I do think that things are unfolding but admittedly more slowly than I think many of us would like.

COL DINIEGA: If we were to get a manufacturer, how long would it be before the vaccine would be?

DR. HOKE: Well, assuming that they would have to actually build a facility, three years I suppose, probably at least. These are a lot of issues that are involved here in terms of economics. This really is a very important effort in my opinion because if we can't solve this particularly small problem for a solution for this particularly large problem with some economic model, then we really have to question a lot of what we're about.

In my thinking about it, I think we can get a manufacturer but have an appropriate price for the product that allows somebody to make some money doing it.

Making a profit isn't evil, but we always try to make things so cheap that we can't

sustain the production. It ends up being completely self-defeating in the long run. So there are a lot of these issues that will have to be addressed.

PRESIDING OFFICER LaFORCE: Joel, then Rosemary.

DR. J. GAYDOS: Joel Gaydos, Department of Defense Global Emerging Infections System.

I'd like to point out that right now in U.S. military, we are probably at the lowest level pressure that we have seen certainly since the beginning of World War II. The numbers of people who are coming through the basic training centers are small in number. There's not a lot of concern about furnishing people to the line, as Jim Neville mentioned.

When we look back and we look back at what happened during Vietnam prior to the time that we had the adenovirus vaccines, we had basic training centers that were on the verge of being shut down. We essentially had to shut down basic trainees at Fort Dix in 1976 during an adenovirus Type 21 vaccine, a Type 21 outbreak, when we were using the Type 4 and 7 vaccines.

I wonder whether we have had any

high-level person in the Department of Defense Health Affairs or within the medical community go to the Secretary of Defense or someone at that level to say, "This is a potentially fatal disease. We have had a lot of seriously ill young people. Somebody is going to die."

There was an outbreak of Type 11 a couple of years ago in a job training center, and the young person almost died. It turned out that this individual was an asthmatic and they almost lost that young person.

I think that Greg Gray is right. We're going to see somebody die of this. And I would not like to be the one to go in front of the microphone and explain why that death occurred.

The other thing is that if we have a buildup or if something happens, we are running a very great risk of having a training post shut down.

Now, the Air Force and the Navy are operating on one training site. And I think that both people have demonstrated that those training sites are terrible in terms of space, in terms of ventilation.

And if we start building up at those two

sites, -- you saw what Lackland looks like now -- this is, as I said, I think the lowest point in terms of pressure and training pressure in the military since World War II.

If they start building up, what are they going to do down there? And what are you going to do when you have people who have totally taken over your hospital when you can't conduct any training at all because of people who are ill? You've got to shut the place down and let it cool off and hope that you can start it up again.

That is something we had to do with meningococcal disease. And, as I said, we had to do it with acute respiratory disease due to adenovirus -- and influenza didn't help either -- at Fort Dix.

So these are situations that I think we're going to see. And I think what you saw presented here and which you have seen in the literature in the last five years are indicators, are warnings that this is going to happen.

I think somebody has a responsibility to take this to the line and the people who don't seem to be very impressed by this and say, "I am telling you this. And when it happens, I hope that you

will be prepared to go in front of the microphone and explain what happened."

PRESIDING OFFICER LaFORCE: Rosemary?

DR. SOKAS: Yes. I think that as a longstanding Board member, it's true that maybe there is some good laboratory research that has come out of this, but certainly for the epidemiologic information, for the environmental assessment information, for the vaccine development information, apart from any potential entertainment value as a historic reenactment, this is really not something that we should be having to address over and over again.

Maybe the one thing I would say is that the economic analysis portions have seemed to be sort of a little bit more seat of the pants. And maybe we should as a Board invite an economist onto the Board, one.

And, two, I think it would be very useful if Colonel Diniega might, for example, go back through the resolutions that the Board has made about this issue over the past at least five years, I think, and say, "Who were they made to? What was the response that occurred from it?" And maybe we need some kind of self-assessment of how

often we say things, to whom we say things.

There might be a learning opportunity here for us as a Board to see where we might potentially either through repetition or volume -- I don't know what -- maybe achieve a little more for our efforts than we seem to have in this particular instance.

PRESIDING OFFICER LaFORCE: I wonder if I could ask Dick Miller to say a few words. Dick is staffing an IOM committee that's looking at vaccines in the military.

One of the important issues or discussion points for the group has been the use of adenovirus 4 and 7 as a case study to actually sort of outline difficulties in terms of vaccines in the military. Dick, would you mind?

MR. MILLER: Just an observation that this committee that we put together at the request of Charlie Hoke is looking at the whole issue of research development and deployment of vaccines that the military uses.

The adenovirus vaccine is a case study for this group because it is, in fact, a research and development triumph and a policy disaster in some other cases. And it's a paradigm for some

other vaccines, such as the plague vaccine, perhaps even the yellow fever vaccine, because there is insufficient economic incentive for big pharma, as they call themselves, to make these vaccines, make them and deploy them year after year after year.

So the adenovirus vaccine is one of several orphan vaccines, in the view of this committee at least. And we have on the committee three representatives from the pharmaceutical industry.

And we're hearing from CEOs from the pharmaceutical industry. The jargon that they use is incentivizing pharma. How do you make it work, their effort to do the R&D, and consistently over time produce vaccines in accordance to the military? Marc is a member of this committee.

PRESIDING OFFICER LaFORCE: Well, I happen to agree with what Joel was saying. As a matter of fact, when we discussed this within the IOM committee, the committee having heard presentations from Charlie, General Parker, and also going back to the documents, where we have, what, 10 or 15 individual statements by the AFEB in terms of the importance of adenovirus vaccine, I think pretty much from the public health

standpoint, everybody feels very sort of frustrated with this. And this may be one of the instances where a clinical incident is going to drive the change.

I happen to think, exactly as Joel does, that you can't have thousands and thousands of cases without the bell-shaped curve exercising its inexorable power. There is something that is going to go wrong on the right-hand side of that curve, down at the .0001 level, just enough individuals have to get infected for something that happened to have either a case of either meningitis or disseminated viral infection with ARDS and a death.

My sense is that -- and this is unfortunate, but I think that is going to happen. When it happens, that 50 million is all of a sudden going to be 300 million with everybody yelling at everybody else in terms of why this happened.

DR. J. GAYDOS: I think another possibility is that a link between a military outbreak and a civilian death is going to be made and the same sort of situation is going to go on.

PRESIDING OFFICER LaFORCE: Yes?

PARTICIPANT: Like with JE vaccine, the Board recommended for at least five, six years to

give a vaccine. We got it FDA-approved, never happened until we had a few Marines turn into basket cases in Okinawa. Then it moved. And I'm afraid this has happened here again.

PRESIDING OFFICER LaFORCE: This is why I think one of the questions that I had about: All of the cases that were followed up clinically, were there any that had positive chest X-rays? That wasn't very clear to me during your analysis.

LTC NEVILLE: Of the inpatient records that my team reviewed, 25 percent of those chest X-rays had some abnormality, pneumonitis, fluid, something, something around in there.

PRESIDING OFFICER LaFORCE: Thank you. I wasn't sure if I heard that correctly. All right.

DR. J. GAYDOS: If you looked at Number 7 in your references, this was a poster at the International Conference on Emerging Infectious Diseases. And Dr. McNeill has listed the breakouts for the chest X-rays.

LTC NEVILLE: If I might add two comments?

PRESIDING OFFICER LaFORCE: Yes, of course.

LTC NEVILLE: The line commanders, at Lackland anyway, the 0506 level are very worried about a potential death because they're the ones who end up getting all of the press and the mothers calling and whatever. In my mind, it's a difficult thing to get that up the chain we all just talked about.

To go back to that deployment question, my office also does DNBI surveillance for Southwest Asia. About a month ago, there was an upswing in respiralis rate cases. So we asked them a question: What do they think it's from?

The response was: We think it's adenovirus. Well, I thought that was very interesting. Let's see if it is. Well, two days later, that group was rotating back to the States and they were getting a whole new group. So we never figured that out.

Our intent is to try and get some of this like an influenza surveillance or respire illness surveillance in that deployed setting to see if that adenovirus is a problem there.

PRESIDING OFFICER LaFORCE: The other thing is if under the best of situations it was like three or five years, even under the best of

situations, where a vaccine would then become available, it may be worthwhile going back to the AFEB documents from the '50s, where they did look at square footage per bunk, the head-toe stuff.

I remember looking at that as an EIS officer when I worked up an Adeno 4 outbreak at Cape May, but I must admit I haven't looked at that or I haven't refamiliarized myself with that obviously since the development of the vaccine because the problem sort of disappeared.

One of the things that I'm sure is problematic is what Steve and I were talking about when we were looking at your CO_2 curves. The temperature of 85 degrees, the relative humidity of somewhere around 80 percent within that room, that sounds like a submarine where something has gone wrong.

There's no outside air. It's all ventilated. It's not filtered. And so I would say just basic principles, somebody would say, "Time out. This is just not right."

DR. OSTROFF: And it is certainly not conducive to learning.

(Laughter.)

DR. SOKAS: It might be a great project

to look at that data and look at the test scores or something.

PRESIDING OFFICER LaFORCE: Other comments? We're going to let this go for a while.

LTC RIDDLE: Yes. Rick Riddle from the Health Service.

That was our comment. I have to reinforce a comment, get this up on the line side. I mean, the consensus with Dr. Bailey was with the SGs and with Health Affairs.

So if you want the services' support, you have to convince your SGs and you have to convince the line side that this is an important enough issue to pursue the expenditures of dollars.

And you just can't go in without the data, and the data are built in the surveillance system that's in place. But I think you have to keep pushing the issue.

Again, just like you say, 3 years, 4 years, maybe as long as 12 years before you have a vaccine on the street and available. You can't overemphasize preventive measures again or --

DR. OSTROFF: One real quick question. I don't know if Greg may address this. I mean, in terms of looking at some of the potential other

indirect effects of more adenovirus, has anybody been looking at, for instance, rates of asthma? Have they been going up over the last couple of years?

CAPT GRAY: We've been looking. I mean, the idea is: How do we break this stalemate without having a death? So we actually have had some projects, and asthma was our first one.

It's a long story, but we looked at throughout the DOD hospitalizations with asthma. And then we had a window, previous hospitalizations with pneumonia, and haven't found an association.

So we're examining now in a cohort of trainees: Of those that had an FRI, are there chronic disease sequelae, such as asthma, to try to see if there is any chronic disease we can point to?

We're all frustrated. Everybody in this room for the most part favors bringing this back, but it's a matter of getting it up where this is up there competitive with the other pressures.

LTC NEVILLE: It's also a matter of resources. We'd like to do more intervention studies or following these people over time, but who has the staffing and manpower to do that with

all of the other stuff?

PRESIDING OFFICER LaFORCE: Yes?

COL DINIEGA: For the record, the Board in 1991 made a recommendation for essentially universal use of adenovirus for recruits. In February of '95, as the reality for the manufacturer, the producer might be pulling out, those issues came up.

In Utah, at one of the meetings in Utah, the Board made a recommendation about the diagnostic capabilities for adenovirus laboratory support, which was dwindling at that time in the military, and also the fact that we needed to make sure that we continued to have the vaccine available. That was in February '95.

In January '98, as the actual shortage started and it was looking more and more bleak and there was some rationing of the vaccine, the Board again made recommendations about the need for continued use of the vaccine and for diagnostic capabilities.

PRESIDING OFFICER LaFORCE: Okay. Yes, Bill?

DR. BERG: Bill Berg.

Has anyone gone back and looked at how

effective these older measures, such as head-to-toe, sleeping arrangements, are? Did anyone do any studies back then?

One of the things that strikes me is that those were all before there were meningococcal vaccine or adenovirus vaccine. They may have been done simply because that is all there was that could be done.

PRESIDING OFFICER LaFORCE: No. To my knowledge, those were controlled studies.

COL DINIEGA: I think at one time -- oh, Captain Trump is here. I thought at one time the CHPPM Disease Control Section was going to look at NOVARDI, as I think -- I don't know who coined that term. I think it's a Mangism, Roberta Mang who used to be at Disease Control.

I thought they were going to do that mainly because the reality was we have no vaccine and we keep pushing all of these administrative or non-vaccine-related control. And we never knew how effective those were.

I thought at one time they were going to do that, then the hand-washing and the air quality, et cetera.

LTC NEVILLE: They've got a resource

problem. People PCS out, and then there's no interest and other people are coming in or whatever. There are so many other things happening there are not the resources to apply to those kind of laid-out --

DR. HOKE: I just want to say one thing. Now, you know, when you look at your life, you try to ask: What have you done that's effective? The only thing that I can say that has worked is that I went to see General Blanck when he was Surgeon General on another matter.

I sort of pushed onto the table -- I later learned that this was extremely forbidden to do this kind of thing -- another matter, which was the adenovirus vaccine. I told him that there was embarrassment enough for this story to go around. Those were the words I used. And it was shortly after that that the 14 million appeared. It's hard to connect one with another, but I think there was a causal relationship.

We have a new Surgeon General in the Army. He recently sent out a sensor, a person to go sense the tenor of the realm. And they wanted to know what should they attend to in the first 90 days. I told them I put on my list, you know:

There's only one thing that you need to pay attention to, and that's adenovirus vaccine.

I sent that about a month ago, and it's gone wherever it has gone. But there is a new Surgeon General in the Army. Maybe it's time for the AFEB to summarize its stuff and come out. There's a new one.

I urge the rest of you who have contact with other Surgeons General when you have the chance. These are precious moments as a professional person to influence these people. Get it into their minds that this is a problem because Health Affairs will turn to those people, those three-stars, and say, "Is this anything? Is this a real issue? Should we support this?"

You know, it really does come down to kind of politics in the end, but it seems to me that's one way to get support. It has worked a little bit in the past and may be what we need to do to sustain this.

In my opinion, it is a funding stream that is going to need to be -- this 14 million is just a one-time-only. We need to develop a real mature plan that has funding to get the job done.

DR. ENGLER: I just have a question and

actually a suggestion. And that is, as many of you know, I am a clinician. I several years ago said to this Board: Do you all care that a large part of what you do is unknown to the majority of the military services, much less the medical community within the military services, and that that's tragic and that there's a real problem in communication?

The clinicians feel the policy-makers are fairly disconnected from clinical reality. I understand the perspective of data-driven communication, but I'm going to tell you that the vaccine no experience that the CDC is going through is teaching them.

There was just a meeting this weekend of anti-vaccine groups, and the CDC was stunned by their improved organization, their visibility, their passion, their loyalty.

And I'm telling you one of the things we all have to do is be compassionate in the way we communicate. And that's not necessarily only data-driven. That means we have to capture people's imagination.

And I will say that some of the clinical perspectives -- if you had somebody stand up there

and talk to the people who are making policy from a clinician who had to be in that hospital during that epidemic and describe the risks and the concern and extrapolate to a future scenario and make them vivid and real, not just dry numbers, you might get more response.

And in that regard, Major General West, who is a two-star Marine Corps general right now in the Pentagon on the operational side, I'm very impressed that he can understand that. And he very much understands the marketing risk for the military if it doesn't address the ends of one and the fallout and the people who have adverse reactions and the problems.

He is very open to input, and I would strongly recommend that this Board consider also communicating their concerns to him. And he can perhaps go to the Joint Chiefs and engage the line advocacy because I'm impressed over the years that I hear things in committees about so and so doesn't hear or listen and then I have an opportunity to talk to a senior line general or admiral and explain my frustration from the clinical perspective. And they go: Oh, that makes sense.

Who is briefing these people? is my

question. And are we doing enough within the military to do positive advocacy for the importance of issues in effective ways? I'm telling you dry numbers don't always cut it. It takes more than that.

And when the civilian world has learned that with lobbying in Congress, there's no reason why we can't do it if it's for a good cause. Certainly bring the data. Bring a little bit more of the data to the table, which is the real impact.

I think what the gentleman said, you know, a base closes, and people are going to ask you in leadership why you didn't do something. And then that begins to touch them where they live. How do you justify these documented decisions over five years? You were warned about this, and you didn't do anything.

People don't look at it that way. They think: Oh, it's another dry report. Let's put it on a shelf, no big deal. We're all sitting here wondering: Is anybody home? But you've got to make it visible.

PRESIDING OFFICER LaFORCE: Okay. We've got to close this discussion and move on to hepatitis C. We will revisit this because I think

I'm sensing that there's a need for us to sort of be lots more active in this arena.

DR. ENGLER: Proactive.

PRESIDING OFFICER LaFORCE: Proactive. Thank you.

Captain Hyams, Hepatitis C? Yes?

HEPATITIS C IN THE MILITARY

CAPT HYAMS: I'm Captain Craig Hyams. I'm the Director of Epidemiologic Research here at the Naval Medical Research Center. I'm going to provide the initial part of this presentation, and Colonel Rick Riddle will end up the presentation.

Next slide, please. Next slide. Let me just mention what's in the next slide before we get there. We're going to eventually discuss the hepatitis C virus infection. And then we're going to go on to our recent DOD investigations and finally discuss the policy implications of our research findings.

Next slide. Let me just say something briefly about hepatitis C virus. It's an RNA virus that was first identified in 1988. Commercial tests were only developed in the early 1990s.

I think it's important to keep in mind that we have only had ten years of experience so

far with this virus. So we're still learning a lot. It's early days for our understanding of this particular infectious disease.

It's predominantly transmitted through large or repeated direct percutaneous exposures with infected blood. At best, sexual transmission is inefficient. Also, you couldn't expect transmission from the blood of an infected person coming into contact with intact skin of a person who is not infected.

As I've said, the natural history is incompletely understood now. Drug therapy can be toxic and is not always effective, but certainly drug therapy is improving.

Next slide. Okay. The factors associated with transmission are blood transfusions prior to the time where we could screen blood donors. Injecting drug abuse certainly is highly associated with hepatitis C transmission. It may be associated in some cases with employment and patient care in the clinical laboratory and may be associated in some cases with exposure to multiple sex partners.

In studies conducted in the United States, there has been no clear association between

hepatitis C infection and military service, medical, surgical, or dental procedures, tattooing, acupuncture, body piercing, or foreign travel. It's important to keep that in mind.

Next slide, please. The highest prevalence of infection is in hemophiliacs treated before 1987. And, again, as I mentioned before, we have a very high prevalence of infection in injecting drug users and then also in transfusion recipients from HCV-positive donors. This doesn't happen anymore.

Next slide. Okay. Let's talk about the epidemiology of hepatitis C in the general population. There's been one large study conducted by the CDC that involved 21,000 surveyed children and adults.

These are individuals six years of age and older. In their study, which was published in the New England Journal, I believe, last year, the overall prevalence of infection was 1.8 percent. It was higher, had a higher prevalence of infection in African Americans.

If you look at the age group that's more relevant to our military population of persons 20 to 59 years of age, the prevalence was higher in

men, 3.7 percent, and lower in women, 1.6 percent.

I think it's important to note that in military veterans, the prevalence was actually lower than the overall prevalence. It was 1.2 percent. So when you surveyed veterans in the general community, not veterans who are seeking care within a VA medical facility, actually, their risk of hepatitis C infection is lower than in the general population. And the CDC has data that the incidence of HCV infection has decreased during the last ten years.

Next slide. Okay. Let me say something about -- these are mainly studies I was involved in when we first developed the second generation diagnostic test for hepatitis C in our military populations.

Samples we collected in 1990 and 1991 from blood donors throughout DOD, approximately 6,000 samples, we found a very low prevalence of infection, as you would expect, 0.2 percent.

Amongst recruits -- this was an interesting study that was conducted by Dr. Leonard Seeff and Dr. Miller, who is here today. In recruits from 50 years ago, they sampled over 8,000. They had samples from over 8,000 recruits.

They found a low prevalence of infection of 0.4 percent. This is before we had heavy use of drugs or thought to be before we had heavy use of drugs.

In a study of recruits of Navy and Marine Corps recruits in 1989, we found a similar prevalence of HCV infection, 0.3 percent. And then, finally, in deployed personnel, -- this is Navy and Marine Corps personnel again -- samples collected in 1988 and 1990, 3,000 individuals, we found a prevalence of infection of 0.4 percent.

Next slide. Okay. There have been recent concerns about hepatitis C infection in our veteran population and amongst military personnel. There has been increased detection of HCV infection among veterans seeking care in VA facilities. During the last five years, they have shown a marked increase in the number of veterans who have been found to have this infection.

A high prevalence of HCV infection was found in two VA patient populations. These are two studies that were conducted. One in Washington, D.C. found a prevalence of infection of 20 percent. And then one conducted in San Francisco found a prevalence of infection of 10 to 19 percent.

Also, the VA conducted a national

screening day in March 1999. And they asked veterans in their facilities on this particular day to donate a blood sample for screening for HCV infection.

Twenty-six thousand veterans agreed to do this. They found a prevalence of infection of eight to ten percent. So, at least within VA facilities, a patient seeking medical care, they have a very high prevalence of HCV infection.

Next slide. Let's talk about our study. Because of a number of reasons which Colonel Riddle will go into, we conducted a large survey of HCV infection in our own military population.

What we used was the serum repository because the samples were available. We took samples from 1997 in a randomized study of over 20,000 military personnel.

Nineteen ninety-seven at that time was the last year that we had complete data for the serum repository. As you know, the serum repository, the samples are collected initially for testing for HIV infection.

They're collected from recruits. They're collected from active duty personnel and selected reservists about every one to five years,

and they're collected before major overseas deployments.

For the year of our study, 1997, about 60 percent of our active duty population had a sample collected in that year. We did a randomized survey of active duty personnel, recruits, selected reservists. And we over-sampled various populations.

We also conducted a study of hospitalization within DOD hospitals during the last 20 years for acute viral hepatitis. Then finally we did a cost analysis.

Next slide. These are the prevalence estimates from our randomized serosurvey of troops in the U.S. military in 1997. And our first large population that we studies was active duty troops. We evaluated 10,000 active duty troops. We found a prevalence of infection of essentially 0.5 percent, which is substantially lower than what was found in the general civilian population.

Among reservists after age-adjusting the data, we found essentially the same prevalence of infection. We age-adjusted it for the active duty troops because reservists tend to be five years older than active duty personnel. Amongst

recruits, we actually found a much lower prevalence of infection, 0.1 percent.

In our over-sampled populations, we again didn't find any increased prevalence of infection. You see slightly increased rates for different groups here, but this is due to the fact that most of these groups except for the women personnel are older than the general age of our active duty troops.

The Vietnam-era troops, these are individuals who were on duty prior to 1994 who were still in active duty in the U.S. military. There has been some concern that the Vietnam-era troops at most risk of infection. So we over-sampled this group. Actually, they had a lower prevalence of infection, considering their age.

Next slide. In most of our sample populations, we found a clear age trend in the prevalence of infection. The 10,000 active duty troops, the prevalence in individuals less than 35 years of age, 0.1 percent, was the same as in the recruits. Then it progressively increased to where our prevalence was 3 percent in those troops who are 40 years of age and older.

We found a higher prevalence of

infection in non-white racial ethnic groups and enlisted personnel. It's interesting in a multi-variate analysis. When we put these factors into the same model, the variable for race/ethnicity actually dropped out of the model and enlisted rank remained an independent risk factor for HCV infection.

Next slide. Okay. We were also able to calculate incidence data. Our serum repository samples are collected serially while a person is in the military. So in many cases, we had more than two samples. And we chose the oldest sample of the individuals who were selected for our study.

In our population of 10,000 active duty troops, a previous sample was available in over 7,000 of these individuals. They were collected one to 11 years apart, for a mean of about five years between samples. And this provided us a very large period of exposure of data we could analyze, 34,000 person-years.

In this extended period of exposure, however, we only found six who seroconverted in this study. That provides an annual incidence of 0.018 percent, which translates into 18 new HCV infections per 100,000 troops each year.

Next slide. We also evaluated genotype. This work was done at the CDC by Dr. Alter. We evaluated 94 anti-HCV-positive samples. These were immunoblot-positive samples. And we were able to detect RNA in 81 of these samples.

We predominantly found genotypes 1A and 1B, which is what you found in the civilian population. So it looked like the transmission was following the same patterns that we find in the general population.

These numbers are small. We didn't find any clear associations with any of the risk factors that we could evaluate or any of the demographic data, but, again, the numbers were quite small.

Next slide. As you can expect, when you screen a large population that has a very low prevalence of infection, we found a lot of false positive results. In the 10,000 active duty personnel, we had 90 samples that were repeatedly EIA-reactive. However, just over half of them were immunoblot-positive, RIBA-positive.

The IND here represents indeterminate. Sixteen of the EIA-reactive samples were indeterminate by RIBA. Amongst recruits, we actually found more indeterminate samples by RIBA

than we found that were positive.

When we attempted to do PCR on all of the 19 indeterminate samples, all of them were negative by PCR, which indicates to us that the indeterminate samples were really false positives.

Next slide. Okay. This is the hospitalization data for acute hepatitis. This is total admissions for all types of acute hepatitis. This work is being coordinated by our Captain Greg Gray.

We have good Navy data on hospitalizations for hepatitis going back to 1975. And then beginning about 1989-1990, we had DOD-wide data.

As you can see, the hospitalizations for acute viral hepatitis progressively decreased during this period of time. Some of this decrease may be due to the fact that we tend to hospitalize patients less often now, but we also feel that much of this decrease is due to the fact that acute hepatitis is less of a problem aggressively in our U.S. military.

Next slide. This is where Colonel Riddle comes in.

LTC RIDDLE: I wanted to just spend the

last three slides on health policy, where this came from. For DOD, we didn't have any routine screening in 1998 except for our blood donors.

And not only in the F.Y. 1999 Armed Services Committee report but also in F.Y. '98, we had received direction from Congress to take a look at hepatitis C in the military.

There was tremendous pressure on Congress from the veteran service organizations, the drug companies, individuals like Dr. Koop and others, to pressure the Department to institute total force-wide hepatitis C screening for recruits, active duty, and individuals separating, very similar to what we had with our HIV program.

I remember in I guess December of '99, there was a full-page ad in the Washington Post by Schering-Plough that said if you had ever had intravenous drug abuse, you needed to be tested for hepatitis C; if you were ever on active duty service or in the military, you needed to be tested for hepatitis C.

So they were certainly trying to create a perception that military put an individual at high risk for this infection. And they were using a lot of the data, some of the anecdotal data and

other data, from the Department of Veterans Affairs to support that.

In '99, the Congress directed us to do a study and to advise on the feasibility of testing for hepatitis C, recruit, active duty, and at separation and discharge.

Next slide. So, in addition to the study that Captain Hyams discussed, which I think was a monumental effort, you realize that in less than six months, we conducted probably the largest seroprevalence, seroincidence and genotypic study that has been done on hepatitis C in the United States.

In addition to that, we did a cost-benefit analysis and worked with Margo Krauss and Rene Howell up at AMSARA to look at the figures and what it would cost us to do a force-wide screening program looking at recruit, all active duty, Guard, and reserve, and then at separation and retirement.

And I guess just focus on the figure down there for greater than 35 years of age. if we did offer testing to that population, that would be the cost.

Next slide. The importance, really, is

this last bullet. If you look at our data, 87 percent of all personnel with hepatitis C virus infection who are currently active duty, Guard, and reserve were individuals who were greater than 35 years of age.

So we worked very closely with CDC and actually contributed to the development of the national policy on hepatitis C with CDC, and they're very thankful for that and, in addition, formed an interagency hepatitis C working group with CDC, NIH, the Department of Veterans Affairs. And it has really paid tremendous dividends for the Department as we have addressed these issues both in Congress with the media and with veterans.

You know, kind of the equation that we use in Health Affairs or Health Policy is "Health policy equals science divided by media squared times politics cubed."

We feel that with this study right here, this was a political issue, which we were very quickly able to bring some science to the table and make a data-driven decision.

Literally, that decision was to offer testing of individuals who separate or retire who are greater than 35 years of age. That creates

service connectivity for that individual. In other words, they now have documented in their medical record that they were positive for hepatitis C while on active duty.

So if they're not at issue for receiving follow-on care and treatment, both in DOD and VA, once they separate from service, it also addresses the individuals who had infection.

We offer that screening based upon a review of risk factors or if the individual just wants to be screened, then they're offered to be screened and that documented in the medical record. And it's just an assessment made of their health and then an advisement on prevention factors because certainly hepatitis C morbidity is associated with a lot of co-morbid factors in an individual as they grow old.

Next slide. So, in conclusion, what we found is hepatitis C three times lower infection in the U.S. military than what we see in the comparable civilian population. Really, it's a result of overlapping programs within DOD.

Certainly hepatitis C is primarily spread by intravenous drug abuse. And because of our testing and screening for elicit drug use and

HIV, both ongoing and at recruitment, we exclude a lot of individuals.

Our routine medical examinations and screening really promote a fit force and would detect individuals that have chronic symptomatic disease, institution of our blood donor look-back -- or the blood testing in the look-back program and our total force immunization for hepatitis A and then our risk-based hepatitis C vaccination policy.

And, really, our recommended strategy and a strategy that we currently have out for the services and the services are evaluating force right now is a targeted screening of individuals older than 35 because of the low risk overall for hepatitis C in the military.

The last slide relates to the contributors to our study. And right now our data is awaiting publication by the American Journal of Epidemiology. I think this is a real push. We do a lot of work within DOD. The onus is upon all of us to try to get this out into the published peer-reviewed literature.

But for DOD, Captain Hyams and myself, the invaluable support from Colonel Rubertone up at

CHPPM with the HIV repository, that's a tremendous resource for DOD; Captain Trump at Health Affairs, statistician up at USUHS. And then this was supported by Dr. Mazzuchi and Dr. Bailey.

It's kind of funny that this study was actually funded partially from Health Affairs, but we got the majority of our money from the Department of Veterans Affairs and the DOD-VA share money. So we were able to combine some resources to execute this very quickly.

At CDC, Drs. Alter and Han and her staff and then certainly Dr. Leonard Seeff, Margo Krauss, and Rene Howell up at AMSARA all contributed to really pull this off very quickly.

And we haven't been under that much pressure from Congress and others as far as what we have done in DOD. The VA still faces a tremendous amount of pressure because it's very difficult for them to provide care for their individuals who are hepatitis C-positive because it's very difficult to review the records and create service connectivity through a blood transfusion or blood exposure when many of these people didn't have that and they're showing up for treatment in VA for hepatitis C.

Questions?

PRESIDING OFFICER LaFORCE: Questions? First off, congratulations. This is now the second example of the power of this serum or repository. For Board members or for those of you who were on the Board when we had the Lyme disease issue, where there was really a great deal of confusion of whether there was risk or no risk, use of this data bank was able to resolve this issue in less than six months. This is really another very fine example of this.

DISCUSSION

LTC RIDDLE: I think we actually used these samples, our hepatitis C samples, when we did this study.

PRESIDING OFFICER LaFORCE: Super. That makes this really even better. Points? Pierce?

COL GARDNER: Thank you for a very nice study. I guess I'm having a little trouble reconciling the slide that was shown about recent concerns showing allegedly 20 percent in VA population in Washington and 10 percent San Francisco and 8 to 10 percent in 26,000 veterans who volunteer. So those are ten times the level that you're finding.

I know these particular groups -- why

are they so far out of line with what we are finding?

LTC RIDDLE: Well, VA services a unique population. They only service about one percent of veterans. And their average patient is an older male who has a very low level of income.

So they see a very unique population of individuals, especially when you look at San Francisco and the Washington-Baltimore area. So I don't think that it's unusual to see a higher prevalence of hepatitis C in those populations.

When VA actually looked at the data from that one-day seroprevalence study, I think they found that 80 percent of those individuals who were seropositive had a concurrent diagnosis.

Certainly they didn't see a tremendous problem with drug abuse in that population. And they have a unique population of veterans, especially in some of the VA facilities.

Now, if I'm not mistaken, some of the other VA facilities in more rural areas of the country did not see near the rates of seroprevalence that we're seeing in these particular high-risk spots.

COL GARDNER: The site of a recent

upswing certainly seems to be not what you found when you looked at it more closely with this data, I guess.

LTC RIDDLE: Correct, within our active population.

COL GARDNER: I guess the other question: What are you doing about it? Is there a protocol or a follow-up for how we're managing the hepatitis C-positive veteran or solider?

LTC RIDDLE: Within the Department of Veterans Affairs, yes. They had developed a treatment or an evaluation and treatment protocol in conjunction with NIH. And, if I'm not mistaken, NIH currently has an evaluation and treatment protocol and a recommended protocol.

COL GARDNER: The debate goes on early treatment or wait until there is more definite disease.

LTC RIDDLE: Right.

COL GARDNER: And which side of that are you coming down on?

LTC RIDDLE: I think the study of Dr. Miller and Leonard Seeff is very important in this context. That study looking at those Air Force recruits from the '40s and '50s, not a single

individual had any morbidity or mortality associated with hepatitis C virus infection over a period of four years.

And, if I'm not mistaken from talking to Leonard, many were surprised to find they were hepatitis C-positive.

DR. MILLER: It was a small number of people. This was published in the Annals of Internal Medicine January 18th of this year. So you can look at it.

But having a chronic hepatitis C infection is not good for your health. On the other hand, at least in healthy young Air Force recruits from about 1950, there was surprisingly little long-term morbidity and mortality and no case of liver cancer in that population. So hepatitis C is a serious long-term infection but by no means a death.

DR. HAYWOOD: Does that imply there is no one under active treatment in the military right now?

DR. MILLER: I beg your pardon, sir?

DR. HAYWOOD: No one under active treatment for hepatitis C in the military now?

DR. MILLER: Oh, I'm sure there are,

sir.

LTC RIDDLE: No, no. If treatment is indicated, treatment is certainly given. And it's on a case-by-case basis. But for us, if an individual 35 years of age or older who shows up and they test hepatitis C virus-positive, they are evaluated. You look at the liver enzymes, look at the individual Council on Alcohol Abuse, other co-morbid contributors to disease, and then monitor through time.

Certainly individuals are going to react differently. Treatment is indicated in certain instances. And DOD has certain centers of expertise. I think Maury Sjogren at the Walter Reed treats quite a few of these liver patients.

PRESIDING OFFICER LaFORCE: Linda, then Rosemary, and then Bill.

DR. ALEXANDER: I was intrigued at this from a systems perspective and looking back at our previous discussion on influenza. I was struck by how dramatically different they are.

In this last example that you presented, there was clear cooperation, actually some guidance from Congress that led to this effort. There was clear cooperation at the federal level with other

sister agencies.

On the influenza side of the house, there seems to be this deadlock that's occurring within DOD. And perhaps there's a lesson to be learned here.

LTC RIDDLE: Influenza or adenovirus?

DR. ALEXANDER: Well, the adenovirus. I'm sorry. What occurred to me was that maybe there's a chance to partner with other agencies. I think about the American College Health Association. I think about organizations that represent incarcerated individuals or where there are confined individuals where the leaders of those organizations may be interested in the vaccine.

And maybe there is an opportunity to mobilize efforts and work in partnership with them because if there is anything I have learned in the last couple of years of working with Congress, it's that if you lobby, your voice is heard. And if you can bring individuals to the table who have been affected, it carries much more momentum than data that has been compiled over the centuries. So I see the two as actually presenting an opportunity for lessons learned.

DR. OSTROFF: There's lot of lobbying

about hepatitis C.

DR. ALEXANDER: Right, right, right, right.

DR. OSTROFF: If there's money to be made by the pharmaceutical industry.

PRESIDING OFFICER LaFORCE: Rosemary?

DR. SOKAS: This is just a follow-up to talking about the difference in the VA statistics. Were all of those VA data collected from hospitals and hospital populations? Because you know that dialysis units and other people in hospitals are going to have higher rates anyway. So I'm just wondering if part of that is what we're seeing with those differences.

CAPT HYAMS: Most of it was collected from outpatients, but they were all patients seeking care in the VA system. I assume some of them were inpatients, but most of them were outpatients.

PRESIDING OFFICER LaFORCE: Bill?

DR. BERG: Two questions. First, I want to make sure I'm understanding this. You used the phrase "targeted testing at retirement." But it's voluntary?

LTC RIDDLE: Right. What we've done is

we just developed a sheet of questions that an individual takes a look at. And if they feel they are at risk or just want to be tested, irregardless of their falling into one of the risk categories, they're offered testing. But the testing is voluntary, correct.

DR. BERG: My second question concerns the fact that there is a paucity of prospective data on hepatitis C infection. In fact, the first good data sort of looking at it is the study that Dick did that appeared earlier this year.

People have been aware that we're sort of skewed by looking at data that is coming out of transplant centers and so on. Are there any plans for picking up these people that you have screened and following them prospectively? I think we would have a good opportunity here.

There was an article in JAMA about a month ago out of Baltimore saying that this prognosis may not be quite as bad for some people as has been indicated.

LTC RIDDLE: There was a registry developed -- I think Margo Krauss was involved at Walter Reed -- of hepatitis C virus-positive patients in the Army.

Certainly funds are available for individuals who would like to submit protocols. There are the Defense Health Research Program and other venues to do that.

I mean, I wholeheartedly support that. We do need to have more data on the natural history of hepatitis C in these populations, especially in a military population, young, active, healthy who have a healthy lifestyle, follow them through time, in addition to the military, and see what happens.

PRESIDING OFFICER LaFORCE: One last point, Steve.

DR. OSTROFF: One quick question. In terms of the data, were you able to take a look at the individuals who may have been born overseas that were entering the military because obviously from some parts of the world, the prevalence of hepatitis C is much higher and with an increasing number of people coming into the services that are born overseas, it could potentially be an --

CAPT HYAMS: We really weren't able to look at that because, even if you were born overseas, you might be inducted in the military from some location within the United States.

So you can look at induction locations,

but it doesn't necessarily tell you where a person is born. So no, we were not able to look at that.

LTC RIDDLE: But we saw no association with race and ethnicity.

CAPT HYAMS: Yes. On our multi-variate models, we didn't see any association with race/ethnicity at all. So that's some indication.

PRESIDING OFFICER LaFORCE: Again, I'm sure I'm speaking for the Board. Congratulations. This is a very nice piece of work, a very nice piece of work.

Let's finish this morning's session. I want to make sure that we finish so that we've got an hour off for lunch. John Grabenstein will bring us up to date in terms of the Anthrax Vaccine Immunization Program. John, we haven't seen you for several months.

LTC GRABENSTEIN: Sir, you missed me one meeting.

PRESIDING OFFICER LaFORCE: Yes.

LTC GRABENSTEIN: I was in the audience without presenting.

PRESIDING OFFICER LaFORCE: I'm sure you'll note that you were missed.

LTC GRABENSTEIN: Well, thank you very

much.

AVIP UPDATE

LTC GRABENSTEIN: I'm John Grabenstein. I'm the Deputy Director for Clinical Operations at the Anthrax Vaccine Immunization Program Agency in the Office of the Army Surgeon General.

I'd like to thank Commander Ludwig for using the time bomb as the symbol for the -- let's make sure that the written record records various symbology.

As I was looking at her graphic, the only thing I could think of was: How long is that fuse? How long does it take that fuse to burn? I'm the eternal optimist, and I can make lemons out of lemonade.

If that fuse is burning, if the bomb is the threat, rather than the supply, then it's the vaccine that cuts the fuse. The danger, though, as I'll explain to you, is running out of vaccine.

So if I can go to the next slide? The threat is still real. The disease is as lethal as ever. The vaccine is still very good. We now have a collection of 13 safety studies involving over 366,000 vaccine recipients.

My charge is to talk about the slowdown,

but I brought some safety data, some epidemiologic data, I'd like to share with you quickly when I get towards the end of that.

We now have six independent reviews asserting the safety and efficacy of the vaccine. And on October 3rd, the Institute of Medicine will convene an expert panel that is expected to meet for about two years to cover A to Z, 0 to 60, soup to nuts, on the vaccine. The problem, of course, is that our vaccine is thinning. Our supply is thinning.

This is the graph of the numbers of people vaccinated by dose in each of the five services. We're passing 1.8 million doses administered since March of 1998 to 463,000 people.

This is the current force. Last week for the first time, this number actually fell slightly as people are rotating out of the service into inactive status because of our slowdown in administration of doses. So we're going to add another row for the archive to show the total doses delivered, as opposed to the doses in the current force.

Next, please. The 17th of July, Secretary of Defense concurred that we needed to

begin an orderly, temporary slowdown of the Anthrax Vaccine Immunization Program until additional FDA-released supply of vaccine becomes available. So we are implementing that.

The tail, the number of doses administered to folks in the continental United States, was far more than the number of doses administered in the high-threat areas.

So we stopped administering doses essentially in the U.S. and restricted the vaccine to people in Southwest Asia, in Korea for more than 30 days, returning to the 30-day policy, rather than our one-day policy.

We are vaccinating the Marine expeditionary units likely to be committed ashore for long periods of time. We are not vaccinating the sailors who remain on ship in the Persian Gulf, nor the people flying out of Turkey.

Those people outside the high-threat areas are deferring subsequent doses until we get more vaccine back in supply. And we are consolidating supplies of vaccines to basically one clinic on each post or base.

My analogy of not vaccine in U.S. is not exactly right. If there are major units deploying

overseas, we will vaccinate them ahead of time, but we're trying to conserve supply by not sending off a vial here and a vial there and having the waste accompanying that.

Next, please. So the reason for the slowdown is disruption in supply. It is not a political cover, as some people will assert. And we fully intend to resume the full program as soon as supply is available. We are conserving supply to focusing on those at highest risk.

As with any vaccine, there is no increase in side effects from a delayed vaccination, no reduction in protection eventually achieved with a deferred vaccination, although obviously there is a lag with those deferred vaccinations. According to the ACIP and all vaccine experts, one does not start a vaccination series over again. One simply resumes where you left off.

Next, please. So I thought I would read you very quickly some of Lieutenant Colonel Phil Pitman's data from USAMRIID regarding long delays in a vaccination series. The analogy we use for the troops says that each dose of vaccine is like climbing a step on a ladder. Each additional dose

gains you additional antibodies.

And so these are statistics on detectable antibodies. We don't know the concentration of antibodies in the blood that is protective, that is immune-granting. So this is detectable antibodies.

But after the first dose, there is already 60, or 84 percent of, recipients who have detectable antibodies; after 2 doses, 95 to 100. That is not to say that we can stop after two doses and we are satisfied. We are obliged to provide the full series to achieve full protection from a scientific and regulatory perspective.

Now, the Pitman USAMRIID data was in analyzing folks who had returned from the Gulf War in 1992-93. It was 281 Fort Bragg soldiers who had received one, 2, or 3 doses of vaccine 18 to 24 months earlier, during the Gulf War. They were then given one additional dose of vaccine.

And in the one-dose group who had received one prior dose, it was 92 percent had a detectable response, 100 percent in the 2 and 3-dose groups, and in the fold increase in antibody concentrations was actually well above 100-fold antibody rise after that single dose; so, thus,

with the ACIP general guidance as our policy of resuming vaccinations where they left off as soon as supply is restored.

Next, please. The problem is that we do not yet have FDA authority to use vaccine manufactured in the renovated production suite at BioPort.

We await the approval by the FDA of the biologic license application supplement for that new plant. It is a complicated process. It is an iterative process. And we won't use the vaccine until the FDA says it's okay to use.

The best guess on when the FDA will grant that supplement to the plant have been early 2001. It is more likely that March of '01 will be when BioPort turns the data in to the FDA. And it will then take the FDA another month or two to render its opinion. So April or May could easily be the earliest approval date for the new facility.

We have a ticking clock. As of the last inventory in mid August, we had 122,000 doses remaining, about 88,000 in Lansing, about 33,000 on various clinic shelves worldwide.

That according to our best guess is sufficient to carry us through about mid February.

Mid February comes before May. And so we are looking for alternatives on what can be done. We can tinker around the edges.

About the only thing that we can do that will carry us with a vaccine supply out to May or beyond is to stop vaccinating in Korea. About two-thirds of the doses we're administering today are in Korea. About one-third are in Southwest Asia. The only way to reduce consumption to get us through until licensing would be to drop Korea from that proposal.

Next, please. Just for historic perspective, these are some vaccine shortages over the past. Many of you are familiar with various items on this list.

The one I'll point out is the third bullet. The analogy that the nation has faced in 1984 is the one closest to what we face today, and it was the national shortage of diphtheria tetanus pertussis vaccine, where the CDC, the FDA, the American Academy of Pediatrics got together and said, "We don't have enough vaccine to go around. What are we going to do?"

And so they said, "Well, give the vaccine to the people at highest risk, infants

under a year." So they said, "Give doses one, two, and three at two, four, and six months of age. Defer doses 4 and 5 at 18 months and 4 to 6 years." It was, fortunately, able to be resolved within about four months, but it did affect by my estimate at least a million children in just those few months.

We have taken the MMWR articles of that era and retyped them and posted them on our Web site. I can provide copies to anybody who is interested.

Next slide, please. I'll be happy to take your questions on the slowdown, but I want to show you some safety data that I think you'll find rather interesting.

This is ecologic data. This is hospitalizations in Korea from 1993 to the present. And since 1998, everybody has been vaccinated against anthrax.

So while there's a little bit of a normal variation, we think there's not anything drastically different in hospitalizations in Korea, where everybody is vaccinated now compared to historical levels.

The blue line is death due to illness,

any location in the world, any cause, any medical cause. And there certainly is no epidemic of death since we have started the vaccination program.

Next, please. The next two slides are historical data on various diagnoses associated on the internet with the vaccine. If you're in San Diego, the rumor is that the vaccine causes leukemia. If you're on the East Coast, the vaccine causes Guillain-Barré syndrome. Korea, it's toxic epidermal metharlysis or erythema multiforme. East Coast again is aortic aneurysms. And you say that there is no frank change in these overall rates.

Next, please. This is thyroid admissions, connective tissue disease to get at lupus, multiple sclerosis, aortic aneurysm.

Next, please. These are ecologic. Those were ecologic data obviously associated with temporal trends. The more precise way, the more proper way is to compare vaccinees and non-vaccinees more explicitly.

These are data from CHPPM. Similarly, I should acknowledge Naval Health Research Center, San Diego has been developing a comparable ability to do analyses. The reason that all of these colors are on here is because I take these data and

show them to the general troop population and teach them epidemiology in three minutes.

This is rate ratios of hospitalization, vaccinees divided by non-vaccinees, 350,000 person-years of vaccinee time, 2.4 million person-years of non-recipient time.

These are the major diagnostic categories in the ICD-9 system, rates per 100,000 per year in the vaccinated group, in the unvaccinated group. And the green numbers are unadjusted rate ratios, only one being above one.

We then did a standard regression and put up with adjusted rate ratios and associated confidence intervals, none of which is entirely above one. There are some, of course, that are entirely below one, suggesting selection bias.

These are the major diagnostic categories. You can go to the next slide, please. These are some of those same diagnoses that are subject to rumors: leukemia, thyroid, MS, Guillain-Barré, ear, asthma, ulcers, joint disorders, lupus, diabetes, blood cytoric, and that gentleman who thinks diabetes is caused by vaccines.

The folks in the orange column, of

course, are the ones who get interviewed by the media and testify to Congress. The black column is not. There was a -- well, I won't go into that story. I'll wait for your questions.

All of these events happened in non-vaccinees. And most everybody here knows epidemiology and you know the implications of the data.

Next, please. This is to remind me to tell you that the Institute of Medicine starts October 3rd.

The shortfall is quite serious, we believe. The safety data, however, is very reassuring. And we have lots more projects underway. So, with that, I'll take your questions.

DISCUSSION

CAPT GRAY: This is Greg Gray. I just have a question. The epidemiologic page here, when you did your adjusted odds ratios and your multi-variate modeling, did you include a co-variate for pre-vaccine hospitalizations?

LTC GRABENSTEIN: Prior hospitalization was one of the co-variates.

CAPT GRAY: Okay. Okay. Thanks very much.

PARTICIPANT: Do we have a reserve supply of vaccine for contingencies or are we going to continue to draw down on the remaining vaccine supply?

My second question relates to your third slide, where you talk about who is being vaccinated now. And one of your bullets is, "but not forces afloat or aloft." Is that the kind of thing we should be advertising in an unclassified forum?

LTC GRABENSTEIN: I'll take that question first. It's actually explicit in the Deputy Secretary of Defense's policy memo and in the services' implementation orders that are on our Web site. And so it is a public declaration by policy-makers senior to me.

The other question was: Is there a reserve of vaccine or do the numbers I show reflect the reserve of vaccine? And the answer is the 122,000 on the 16th of August was every FDA-released dose in the United States.

And so the policy decision was driven by the need. The threat is now, and we need to protect the forces in the high-risk areas. And so the only doses that we have -- the Secretary of Defense-level authority to reserve past the run-out

data is 1,000 doses for Special Operations Unit, 8,000 doses for the Dose Reduction Route Change Study, and another 1,000 or 2 for odd purposes that I'm simply forgetting.

So the national reserve, if you will, the planning, for planning purposes is the newly produced lots that have not been FDA-released, which would be available theoretically under an IND.

DR. OSTROFF: I remember hearing in testimony a few months back that there was a desire to potentially look for a second manufacturer. Do you have any updated information about attempts to do so?

LTC GRABENSTEIN: The desire persists. If it's three years to get an adenovirus vaccine, it's at least three years -- well, the congressional testimony numbers would be -- I forget -- five to six years or something on that order to get a second manufacturer out.

There are a whole variety of strategies being approached and attempted to try to get around various bottlenecks in terms of the packaging and filling line in Lansing and a variety of things like that, none of which is going to deliver

vaccine in a matter of months, rather than in a matter of years.

DR. MUSIC: Where are we in terms of IM versus sub-Q?

LTC GRABENSTEIN: The CDC is well along in -- well, more specifically, they have received or they about ready to let contracts -- they need to do so by the end of September -- to the study sites that will be the clinical sites for the Dose Reduction Route Change Study.

This study is to see if removing the 2-week dose and eventually the 12-month dose is as immunogenic. And several arms will assess immunogenicity intramuscularly compared to subcutaneously.

We expect to enroll first volunteers in February or so. So things are moving along nicely.

CDR MURPHY: How many doses will be consumed by then?

LTC GRABENSTEIN: The first two years is 7,600 doses, something along that line. Actually, we're in negotiation to see if we can use an IND lot for that, which would free up those doses for the present. But even that isn't many days worth.

PARTICIPANT: There have also been

questions in the last week about the adequacy of the Fort Bragg study to address the delay between stopping and restarting vaccinations.

We're looking at trying to look at those same sera again using a now validated assay to see if the FDA will accept that as enough data to support the ACIP's recommendation on that.

But you might want to think about another reserve because there could be another requirement for another study coming down the pike to address that issue as well.

LTC GRABENSTEIN: I appreciate advice on how many doses you might anticipate.

PARTICIPANT: Still undetermined.

PRESIDING OFFICER LaFORCE: Yes?

COL GARDNER: This is sort of an interesting age observation. I think Colonel Grabenstein obviously has young eyes that can see six slides per sheet. Captain Gray has been around a while. And so he handles two per sheet. And I guess that means Captain Hyams is about ready to retire because he's got --

(Laughter.)

COL GARDNER: The point I'm sort of leading up to is there are some wonderful tables in

here, but I wonder if we could give a little guidance to some of the speakers for tables like this. You know, two per pages would be a little bit easier on some of us who have been around a while.

LTC GRABENSTEIN: I'll be happy to send you a full set, sir.

COL GARDNER: Thank you.

PRESIDING OFFICER LaFORCE: On that note, Ben has got a couple of administrative things before we break for lunch.

COL DINIEGA: This afternoon's speakers, if you have PowerPoint, please see Specialist Brewer and give him your thing so it can be loaded up.

Lunch is available at the WRAIR cafeteria down the hall, through the long hallway, through the doors, on the left. And we will start at 1:15.

(Whereupon, a luncheon recess was taken at 12:16 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:20 p.m.)

PRESIDING OFFICER LaFORCE: Let's begin this afternoon session, if we could, please. This afternoon's presentation, Dr. Gaydos?

DR. C. GAYDOS: Thank you.

UPDATE ON STDS IN THE MILITARY:

FOCUS ON CHLAMYDIA INFECTIONS IN MALE ARMY RECRUITS

DR. C. GAYDOS: Thank you. My name is Dr. Charlotte Gaydos from Johns Hopkins University. Thank you to the organizers of the meeting for inviting me to share some of the results of our studies on chlamydia in military recruits.

We first began our studies in the military in women in 1996. We were the recipient of a women's health defense initiative grant from the Department of Defense, and we studied female military recruits.

Today most of the focus of my talk will be on *Chlamydia tracomatic* infections in male military recruits, but before I begin, I would like to tell you a little bit about an update on our data from the 1996 to the year 2000 study of women.

I briefed the AFEB a couple of years ago. And, as a result of our studies, your

committee recommended to the military that females be screened. In the packets that are being handed out, you have a group of selected references that we put together.

The recommendation that this group made to the military is listed as Number 4, and that's in your handout. I also call your attention to our Reference Number 2, which is a cost-effectiveness study showing that screening for chlamydia in females is cost-effective.

Every year we have about three million new cases in the United States. Two million of these remain untreated. As I said before, we screened female military recruits and found the prevalence of 9.5 percent. I don't need to tell most of the people in this room that untreated infections can lead to costly sequelae and prolonged transmission between sexual partners.

Since the advent of screening urine by DNA amplification assays, it has been very easy to screen large asymptomatic groups of chlamydia for infection.

First, I'd like to just, as I said, give you a brief update on our studies in females before we turn our attention to men. We have now screened

about 23,000 female recruits, all of these at Fort Jackson coming into basic training from all over the United States.

You can see that we had a rather high prevalence in the South. Overall prevalence was about 9.4 percent. But you can see that the highest prevalence is in the South and the lowest prevalence is up here in the West.

We noticed that for the four years of the study, the prevalence increased from 8.5 to 9.9 percent. And we decided to look at the reasons for this change.

Briefly, we found a very high rate in those women less than 25 years old, a prevalence of about 10 percent. Multi-variate analysis of risk factors showed that, in addition to risk behavior, that the prevalence was increasing independent of whether or not we screened women from different regions and whether or not we screened young people.

We weren't screening more young people over the course of the study, and we weren't screening more people from the South. Although these were both independent predictors, also the year of the study was an independent predictor

using your women's reference.

So we concluded by still thinking that women are at high risk for infection, that we did see some reductions in risk behavior over the time, although not great, young age at the end of the study but still remained a significant risk factor and predictor.

If we looked at reasons why the prevalence was increasing, we thought that probably most of the increase in prevalence was due to the fact that we were having increases in the number of young women under the age of 25 that were screened in successive years.

We also discovered that the geographic region for the home of record that a recruit came from was an independent predictor. Even though black race was predictive of infection, we realize that using race as a tool would not be feasible. So our recommendations at the end of our female study was that a cost-effective, sensitive screening control program would be to base screening based on young recruits.

We also have published the cost-effectiveness study that is Number 4 in your handout. One of the things that we thought about

after doing this study was a good many of the basic recruits that come into the military lead to return to civilian life. And this has been the focus for another and now cost-effective analysis which is going to be published in the October issue of the American Journal of Preventive Medicine.

And you can see here that even though half of the recruits would return to civilian health care; that is, people who were screened in the service in basic training and then went back to National Guard or to the reserves still if we screened women and only looked at a one-year analytic horizon, it was still cost-effective to screen women. Even though the civilian health care sector was reaping much of the benefits in cost savings from the military doing the screening, it was still cost-effective for the military to screen, even looking at a one-year analytic horizon that could save money by screening women under the age of 25.

I'm going to turn now to the male screening since that's the topic of interest today. Our objective in this first prevalence study was to look at the significance of race, geographic origin, and age and some of the behavioral risk

factors, much as what we had done with the females.

We did three different periods of study for the prevalence study. Overall, we screened about 4,500 males within the first week of entering basic training. These were non-health care-seeking population. Overall prevalence for these 4,500 men was 4.9 percent. These came from diverse ethnic backgrounds and represented 50 states and territories.

What we did was offer an educational session on STDs and then tested their urine by ligase chain reaction for chlamydia and for gonorrhea. I won't say anything more about gonorrhea today except to say that our prevalence was only about four percent.

We looked at sexual risk behavior with questionnaires and also gave them -- next slide, please -- a pre and a post questionnaire before and after the intervention of the educational intervention.

Eighty-seven percent were under 25. Sixty percent were white. Eighty-three percent were sexually experienced. And you can see that they practice high sexual risk behavior in that they had more than one partner or a new partner the

last 90 days and only about 30 percent used condoms consistently.

This is a map of the regions, the CDC reporting regions. Again, it looks like the women, the highest prevalence was in the South, with the low prevalence in the Northwest.

Individual risk factors in a multi-variate analysis included being African American, coming from the South or the Midwest, and the risk factors of having more than one partner or a new partner.

We did observe some differences in prevalence by the regional home of record. They were significant in multi-variate analysis when we controlled for age and sexual risk behavior. However, when we controlled for race, these regional differences were no longer of significance.

So our conclusion was that we found a high prevalence of chlamydia. Regional differences may exist, but they may also be due to race. And they certainly are different to age and behavioral characteristics.

I want to focus now on the second study that we did, and that was an assessment of the

behavioral risk intervention. We wanted to assess the feasibility and effectiveness of coupling this screening with an educational intervention in new recruits.

The period of this study that we analyzed the questionnaires from was from August to January, non-health care-seeking. In the study, we analyzed data from 3,000 men. Two thousand had complete data, paired data, questionnaires that we could analyze.

Again, same methods as before. We offered the questionnaires. The pre and post educational intervention questionnaires looked at sexual behavior, susceptibility, severity, and barriers to using condoms. Again, in this population, very similar population characteristics as before. The prevalence was 4.6.

Next. When we looked at the behavioral questionnaire, we found that 88 percent had experienced vaginal sex. Many had participated in oral and anal sex. Eight percent already had a history of an STD. Last intercourse, only 47 percent used the condom.

When looking at the pre and post-intervention data, pre-intervention only 17

percent thought they were at risk for an STD. Afterwards, 34 percent thought they were at risk. We have lots and lots of data that I have handed out to you on the handouts, but I'm just going to highlight some of the more notable successes here.

Using a pair of t-tests, looking at recruits' answers before and after the intervention, we changed the mean score for this question. It was: How likely is it that in the next six months, you will use a condom every time you have sex? And the mean score changed from 3.7 to 3.9, which doesn't sound like a lot but in a paired t-test, it was significant.

This question, "How sure are you that you know how to properly use a condom?"; pre-intervention, 4.6; post-intervention, 4.8, significant. How sure are you that you would properly use a condom every time you have sex? Pre, 4.2; post, 4.4. So they were learning.

So we looked at the feasibility of linking education with screening, and our feasibility indicators were the volunteer rate. It was highly acceptable. The treatment of the people that were infected with chlamydia was 100 percent.

When we queried the questionnaires, five

percent thought the educational session was valuable and that they experienced a learning experience on three percent. The most important aspects of the talk were "all of the above," and that was how and when to use condoms and STD knowledge.

So, in summary, screening revealed a high chlamydia prevalence in males. Young male recruits found that the educational session was valuable. After the intervention, the perceived susceptibility to STDs increased. Knowledge of STDs and condom use improved. And attempt to use and confidence in condom use improved significantly. Then also we felt like several perceived barriers to condom use were decreased significantly.

So we would recommend not just introducing a screening program but to linking it to an educational intervention, also using these educational sessions to increase knowledge for susceptibility and how to use condoms. We think that the educational intervention should be adopted as part of a prevention and control program for military recruits.

Then we need follow-up screening with

more long-term follow-up using urine tests, but we were not able to do that in this study. This second study on behavior was funded by the HPPI initiative, which is the Health Promotion and Prevention Initiative, by the Aberdeen group, the Center for Health Promotion and Preventive Medicine at Aberdeen Proving Ground.

Towards the end of the study, we decided to look at some ways that we could reduce the cost of screening for the military so that we could make an inexpensive recommendation for how to screen men. And so we looked at the leukocyte esterase test.

Previously, the LAT, which measures white cells in urine, has been shown to be useful as a screening tool for detecting your general infections, chlamydia, GC, whatever, in symptomatic men and has shown to be cost-effective; in addition, pooling of female urine. But no one had ever looked at male urine to see whether or not urine could be pooled before the DNA amplification step. Female urine pooling has been shown to be sensitive, specific, and cost-effective. So we decided to look at this for males.

So we wanted to evaluate the feasibility

and accuracy of using the LE test as a cost-saving pre-screening indicator that could predict which men might need to be tested for using the LCR test. And then we, additionally, on the subset decided to evaluate the accuracy of another cost-saving strategy. And that was pooling.

So the period of this study was from April to June of this year. We screened 1,438 recruits. Overall chlamydia prevalence during this time was 3.3. Gonorrhea prevalence was .3. The population was very similar to what we have been studying all along.

Next slide, please. So, again, it is still part of the same program, offering the educational initiative, but in addition to doing the LCR urine test, we did the leukocyte esterase test on 1,438 men. And then on a subset, we did pooling on 944.

We calculate sensitivity and specificity and predictive values for LE and also for LCR. I don't know if people understand or have seem any of the publications about the pooling algorithm, but what you do is you process the urine. And then you put four, and you can even pool up to ten urines in one unit dose of the DNA amplification test.

The most expensive part of doing these DNA amplification tests is the unit dose that you do the test in. So if you put four urines that have been processed in the test and it comes up negative, you've killed four urines with one test. And all of these people are considered to be negative.

If, however, you get a positive pool, then you go back and test the individual specimens in that pool to find out which one is positive. This technique has been used -- next slide, please -- in screening serum for HIV in blood banks, et cetera.

So, looking at the 1,400 people, we found that using LE, we only could obtain a sensitivity for chlamydia for a 45 percent. The LE caught 36 positives that were not positive for chlamydia by LCR. It, however, missed 26. So we had a very low sensitivity.

In looking for GC, we found we had a very low number of positives during this time, but we only were able to achieve a sensitivity of 60 percent.

If we combined the data and looked at what was the sensitivity of the LE for finding any

positive, whether it was chlamydia or gonorrhea, we still only achieved a sensitivity of about 45 percent.

Next we looked at the pooled on 944 specimens. Pooling missed three, but, in addition, LE pools turned up four positive pools, which when we repeated these in a diluted state, 1:4 in urine buffer, we were able to confirm all four of these as true positives. So we missed three and picked up four extra ones that the single test would not have picked up.

Sometimes you have inhibitors to the DNA amplification process in urines. And one way to get rid of inhibitors is to dilute them. So the little trade-off here, you dilute some below the sensitivity of the assay, but you also dilute out some inhibitors so that you can pick up additional positives. So sensitivity final results, sensitivity 91 percent here.

So we concluded that in the non-health care-seeking male recruits, we found a high prevalence of chlamydia. We could not recommend that LAT be used as a pre-screening tool because it misses more than half of the positives, but use of the pooling algorithm is both sensitive and

specific for male urine. And we think that it could be recommended as an accurate and cost-effective screening method in military recruits.

Next slide, please. Just to give you an idea of a hypothetical cost savings, if we were to test those 944 individuals, we would use a 944-unit dose. And if we assumed we could buy those unit doses for $10 apiece, we would spend $9,000 testing these men.

If, however, we put 4 into 2, we only would have to do 236 pools. Then we would retest the ones that were positive and come up with 124 retests by testing the positive pools, and we only used 360 doses for a cost of 3,000, saving about $5,000.

I'll be happy to take any questions. That concludes my presentation.

DISCUSSION

PRESIDING OFFICER LaFORCE: I have one question. I always have a great deal of difficulty with the likely scales in terms of differences between 3.7 and 3.9 in terms of what on Earth does this mean in terms of public health significance.

DR. C. GAYDOS: Well, these are means,

remember.

PRESIDING OFFICER LaFORCE: Oh, yes.

DR. C. GAYDOS: And they're paired t-tests. We consulted with a good many statisticians about the correct test to use for this difference, and we did come up with that these were significant results, that they were learning.

PRESIDING OFFICER LaFORCE: You missed my --

DR. C. GAYDOS: Are you talking about how --

PRESIDING OFFICER LaFORCE: Yes.

DR. C. GAYDOS: -- our public circle --

PRESIDING OFFICER LaFORCE: How are people impacted? Right.

DR. C. GAYDOS: That's a limitation of the study. I mean, if you can't interview them individually, it was our best attempt to on a ten-minute questionnaire assess what they were learning. And if there was something that they learned that caused them to move their scale, then we felt like they were learning.

But certainly more studies need to be done on long-term follow-up to see what their reinfection rate is after they are treated when

they are found to be positive.

PRESIDING OFFICER LaFORCE: Yes?

DR. ATKINS: Dave Atkins.

What was the nature of the educational intervention? How long did it take? Was it one on one? Was it --

DR. C. GAYDOS: No. It was in a group of about 200 men. And it was given by a former Army sergeant who had worked in the troop medical clinic taking care of STD patients.

It was mostly an oral presentation, but we did use some hands-on tools. So I don't know if any of you have seen these large condoms. They call them candoms. They're the soft drink holders. It looks like a condom. And you can unroll it.

So we gave every one of the soldiers one of these to practice putting the condoms on their hands. And as they were talked through by the health educator about proper use of how to use it. And then it was a question and answer period after. It lasted about 45 minutes.

DR. OSTROFF: I'm just curious as to -- Steve Ostroff from CDC -- if you have any information about how this group compares in some of their risk behaviors to a similar population

that's not military recruits.

DR. C. GAYDOS: There have been relatively few studies that have been done in screening males for chlamydia, at least asymptomatic males. Most of the screening that has been done that's been published is in symptomatic populations. There have been a few straight outreach studies and a few screenings in prisons, but there have not been very many large-scale studies.

CDC is currently funding four centers in the United States to do a cost-effectiveness analysis of screening asymptomatic males in preventing sequelae in women at the present time that we're involved in, but we're finding similar rates in at least our population in Baltimore, where we're screening in the schools and a detention center and some outreach vans and also in a team clinic in a shopping mall.

Probably the largest study that has been done has been by Jean Narazzo at the University of Washington. She had a prevalence rate of about five percent. So I think it will compare favorably when we get more data.

PRESIDING OFFICER LaFORCE: Yes, David?

DR. ATKINS: Do we have any data on what happens with young men when they're told they're infected, what portion of them inform their partners, what portion of their partners get treated?

DR. C. GAYDOS: No, we don't because, unfortunately, most of these men -- I mean, they're told when they go to get their treatment that they should notify their partners, but most of them have left their partners in their home state before coming into the military.

They're tested, as the females were, within the first three days of joining the military. So we don't have any good data on reinfection rates either, but we think this is a prime opportunity to treat them when they come into the service because after they finish basic training, then they go on to either their duty assignments or individual advanced training. And we do know there that they are very highly sexually active.

One of the advantages of screening them when they come in as well as screening the women when they come in is just to start out with a clean, treated population.

We know that about 30 percent of women who have untreated chlamydial infections will go on to develop symptomatic or asymptomatic PID within one year. So it makes sense to start early and treat them from the beginning.

PRESIDING OFFICER LaFORCE: Linda?

DR. ALEXANDER: I have problems with this because, as we have talked about with other topics today, it appears that, even though this Board has made recommendations about this topic in the past, those recommendations have actually not been followed through. And I know there are a number of economic reasons.

But it's frustrating as a new Board member to sit here and feel pre-impotent about a topic that's a no-brainer. This is one that shouldn't take a lot of discussion and hammering. It's one where it can make a profound difference in people's lives.

So what is it that we can do to get out of this sort of repetitive stage of saying, "Yes. Let's do it" and wringing our hands about it to actually doing something?

I mean, is there a way to say it with greater impact? Is there a way to be more

effective as a Board? I don't like sitting here feeling like here's a situation that can be rectified, but we are helpless to do anything about it.

DR. ATKINS: Well, can we get some clarification on the practice of screening women? Because I'm not sure. That is a routine practice in all of the services now or it is not?

DR. C. GAYDOS: No, no.

DR. ATKINS: No.

DR. C. GAYDOS: It is not. The Navy has been screening at Great Lakes using GenProbe for a number of years, but I'm not sure if they were thinking about switching over or whether they have switched over to an amplified test or not.

But some of your older tests when you switch from an unamplified test to an amplified test, you will actually increase your prevalence by almost half by switching to a more sensitive test. They did screening on pelvic exams at Great Lakes for a number of years.

The Air Force is just now getting ready, I believe, to institute screening. The Air Force Academy has been screening. We're getting ready to do a prevalence study with the Coast Guard, but the

Army has not implemented screening, to my knowledge, since the recommendation was made by this Board more than a year ago.

LTC NEVILLE: I should emphasize the Air Force recruits in the six weeks of basic training, that screening at that point doesn't exist right now. We're trying to do that.

But in the MTFs, when they go for six weeks of training, it's maybe a couple of months of technical school training and then their first assignment. In those early months, -- and I'm not sure when that occurs -- they get their first annual passes for the first three years, it may be occurring at MTFs.

And most MTFs probably are, but I don't have data to say that it is or it isn't. In the medical setting in the clinics outside of the basic training setting, then it probably is.

DR. C. GAYDOS: We know it was not occurring at Fort Jackson when we were down there because we did the study in Pap smear clinics. And they were not screening. We screened while we were there and did culture to compare.

We found the prevalence in asymptomatic women -- there were 402 women screened. Only two

reported any kind of gynecological symptoms. Many of them were pregnant. We found a prevalence rate of 7.2 percent. So it was not occurring then, and I don't believe it's occurring now.

LTC NEVILLE: But MTF-specific is the point.

COL WITHERS: Is that the training population that you're discussing or in permanent party soldiers?

DR. C. GAYDOS: The Pap smear study was done in active duty women. The only requirement was that they were active duty, but they were mostly young active duty women just reporting for their annual pelvic exam. And it was done at Fort Bragg.

COL WITHERS: Our consultants tell me that you don't have a policy for all the tens of thousands of standards of practices there are in medicine. Okay?

We have maybe 50 policies or 100 that come out of MEDCOM that are enforced at any one time and maybe tens of thousands of standards of practice. So you can't expect there to be a policy for everything. That's one thing --

DR. ALEXANDER: Well, that's the --

COL WITHERS: Let me finish, please. Secondly, my consultants tell me, our consultants tell me, that this is generally done.

DR. ALEXANDER: But we don't see the data, and we don't see --

COL WITHERS: Well, who has it? I mean --

DR. ALEXANDER: I just thought Colonel Neville said we don't have any data on it. And, thirdly, we are developing a policy to catch people in training. We are. It's just that things take time.

DR. ALEXANDER: I guess I find that sort of --

COL WITHERS: From where you sit, you say, "Why don't you idiots do it?" I know what you're thinking, believe me.

From where I sit, I think, "My gosh. I've got 100 things to do today. And this is one of them, and this is months of work."

DR. ALEXANDER: Well, what I'm actually thinking is --

COL WITHERS: By the way, it's not my agency.

DR. ALEXANDER: No.

COL WITHERS: So don't blame me. But I'm telling you it's just not as easy as you think.

DR. ALEXANDER: I am not thinking it's easy. I am just thinking that there are creative strategies to get this done that maybe have not been on the radar screens of the health care providers within DOD, that we have been effective in the outside community by making sure that under-served women in prisons who are Medicaid recipients, women who are in managed care plans get annual testing for chlamydia, the infrastructures there.

So I find it egregious that military women are subjected to less than what is the standard of care across the U.S. for other populations of women.

So I'm not pointing fingers. I'm saying: What can we do about it? Because it would seem that there could be some creative solutions that could be employed.

LTC NEVILLE: I would say once again the standard of care is the same in the Air Force and I'm sure the Army as it is in Kaiser or whatever.

At the training base, when they first walk in the door to the Air Force, they don't get

screened there yet. And we're trying to do stuff. Like was heard before, to get anything done in a training population, that time is so regimented throughout the whole six weeks. To get them to come in and pee in a cup and the positives come back and get treated, contra, all of that stuff is hard to do for a whole variety of reasons.

Once they get to their -- pardon me?

COL GARDNER: The Navy has been doing it and has been doing it for years. And they're every bit as regimented as the Air Force or the Army.

LTC NEVILLE: It's different. And I'm not a line commander of a training battalion either myself, but I'm trying to get into the door just to do this like a pilot study to see if it's feasible. And that's hard to do for a few weeks at a time.

Once they leave that training, they go to their bases. And each MTF has their own medical staff and policies and all of this stuff. That's where that standard of care gets applied. I can't tell you that each MTF has 100 percent screening. We could try to look into that. I'm not sure how easy that would be. I mean, we could select bases or something like that.

I know that the lab, the reference lab,

at Brooks Air Force Base, which is where most of those chlamydia tests are sent, just converted recently, the last year or so, to the ligase chain test.

And the number of chlamydia tests that they have done has skyrocketed, thousands a month. And most of those are from Air Force bases. I can't imagine those are symptomatic cases that are getting sent. I'm guessing that a lot of those are screening tests, but I can't say definitively.

DR. ALEXANDER: Well, one of the things that I just want to put out on the table is that next year we're proposing some legislation for Congress to consider.

This year we did a comprehensive syphilis elimination package. Next year we're proposing that we go for a chlamydia elimination plan for the U.S. That basically means that we would work with Congress to make funding available to the states and for whatever institutions are out there that, for whatever reason, can't seem to get up to speed with chlamydia screening.

Maybe this is an opportunity for DOD to say, "Look, we can't do it. We don't have the resources. It's going to cost $6.2 million the

first year. And that could be a line item in that appropriations package."

I'm trying to understand what the issue is because if you want this to be resolved, there are ways to resolve it. If this is something you are not interested in doing, I'm, frankly, not interested in sitting here wringing my hands about it. I'd like to be doing something.

LTC NEVILLE: Well, I would say -- again, I'm not an Air Force chlamydia person. I don't know anything about policy, but my only point is that all Air Force women may be screened already. I just can't say that they are.

I know they're not screened at basic training. And that would be the easiest centralized place to do some of those studies or whatever, interventions and education, or education.

Once they leave the training, they get scattered to all the bases. Then it's harder to track and harder to get a handle on it. It may well be the case now everybody gets screened.

DR. ALEXANDER: The guidelines say sexually active women between 15 and 24 should be screened annually. I think all health care

institutions have problems with that.

I'm just trying to think of ways that DOD can do a better job and we as the AFEB can help the DOD do a better job in fulfilling this requirement.

LTC NEVILLE: In my mind, the first question would be for us or Bradshaw or someone from Medicare to figure out if the Air Force medical treatment facilities are screening every woman under age 25 who comes in for an annual Pap smear. If they are already, then what the heck? Why do it at basic training?

DR. BERG: I share Dr. Alexander's concern, and I would like to ask: Would it be appropriate to ask each of the three services to give us a report at the next meeting on their screening programs for chlamydia, the success of the screening programs, is the screening actually getting done, and then a recommendation as to whether males should be screened also?

We're frustrated because the Board has brought this issue up. And you're frustrated because you don't have the answers.

CDR MURPHY: Someone may know a little bit more on this than I do. Commander Murphy, Navy

Environmental Health Center.

I'm wondering about the Department of Defense prevention practice program, which is a direct provider to patient programs that does different types of screenings within that, if the chlamydia screening is part of that for the women that are in the military that are between the ages of 18 and 24.

PRESIDING OFFICER LaFORCE: Yes?

COL GARDNER: I just you have raised a generic issue. And the generic issue is a matter of data. In the civilian world, you tell the physicians what the standard of care is, and you expect them to go out and do it.

But nobody counts how many they do. It's the same thing in the military in most respects. The data aren't there, even though we think everybody is out there following the normal standard of care. And the data systems to actually select that kind of data actually would be easier to do because we do have a fairly extensive electronic data system for most of this stuff.

But we don't have resources channeled in to addressing those specific data questions. And I think that's where the AFEB might be helpful, is to

see if you can help get resources directed to actually tracking the kind of data that need to be done to address these kinds of questions.

That's where we have, frankly, the most difficulty. It's not that the data aren't out there. It's that we don't have the resources to put the people out there to go out and pull in and give you a report and tell you how much is being done.

DR. HAYWOOD: Mr. Chairman, I would suggest that we put this on the list of things that need to be considered at the executive session for specific policy actions.

PRESIDING OFFICER LaFORCE: So done.

DR. C. GAYDOS: Even if screening is done at the annual Pap smear, if most women don't get to their annual Pap examination for 8 to 12 months after they've joined the military, fully 30 percent of those women who were infected when they came in will have already developed pelvic inflammatory disease.

There's good data in the literature that has shown delay in even just reporting positive cases in STD clinics and family-planning clinics that the time women come back in three months

later, several of them have already developed pelvic inflammatory disease.

So if you're going to miss 30 percent of your PID by waiting a year, then we would recommend that the best place to institute the screening would be the day they walk in the door. This also cuts down on your transmission also to the men and eliminates a lot of the potential for reinfection.

It's the reinfection in these asymptomatic chlamydial infections that are doing the damage to the Fallopian tubes and ending up in infertility and pelvic inflammatory disease.

PRESIDING OFFICER LaFORCE: Joel?

DR. J. GAYDOS: Joel Gaydos.

I just wanted to point out to the group that in your handout of references, Number 3, which is an abstract by Mary Ann Shafer and her group in the California area, the Marines -- and I think the Marines deserve some credit -- are screening all their female recruits for chlamydia and gonorrhea and doing Pap smears on them. So, in addition to taking care of their recruits with influenza vaccines, they do a number of other things.

I would also like to point out that the cost-effectiveness analysis that you have in your

packets was done using the actual costs of this program at Fort Jackson, which actually went on while they actively trained and processed recruits. It was integrated right into the training process for a period of years. What you see in that cost-effectiveness analysis is the actual cost of what it took to do that.

So we've got a lot of experience in the training centers.

DR. C. GAYDOS: In that analysis of a cohort of 10,000 Army women coming into the military in that publication, there would be expected to be 276 cases of pelvic inflammatory disease developed by the end of the first year, of which 222 of those could be prevented by adequately screening and getting these women treated early. And that's for just a cohort of 10,000 women.

You multiply that by how many women are coming into the military. Fully I think between 18 and 20 percent of all new military recruits are women now.

CDR LUDWIG: Yes, sir. Dr. Ludwig again.

I just want to offer this as information. The STD Prevention Committee that I

mentioned in my report recently -- I believe it was in July -- had a meeting where the preventive medicine officers from all of the armed forces reported on their STD screening policies during basic training.

It might be useful to have a representative from the STDPC come and speak to the Board to summarize that information from that committee, rather than have a service report.

COL DINIEGA: They are already on a preliminary schedule for the next meeting. The STD Prevention Committee and also the PPIP Implementation Committee to give an update on PPIP implementation and also almost a formal suicide prevention committee at the DOD level are all on tap for the next meeting.

PRESIDING OFFICER LaFORCE: Thank you, Dr. Gaydos.

DR. C. GAYDOS: Thank you.

PRESIDING OFFICER LaFORCE: We will continue with this tomorrow.

Major Pavlin, BW Syndromic Surveillance. Apparently there's a GEIS workshop.

Actually, before we begin, could we send these down? I want to take one minute before too

much time goes on. What is going down is my hand-drawn map. Now, please, please. Things will start at my place somewhere around -- we will probably finish at 4:30-5:00 o'clock. And Pierce and I and maybe Stan will go down early.

And we would say that as soon as you wish, please come by. It's at 1406 27th Street in Georgetown. There are two Metros that are fairly easy to get to, and what you have is a hand-drawn outline of where those Metros are. One is Foggy Bottom, and the other is Dupont Circle. The easiest --

COL DINIEGA: Two different colors, now. The Foggy Bottom is the blue line.

PRESIDING OFFICER LaFORCE: Yes.

COL DINIEGA: And Dupont Circle is the red line.

PRESIDING OFFICER LaFORCE: Okay. The easiest is the red line. They're both about the same distance. They are a 15-minute walk. But if you get off at Dupont Circle, all you do is come out on Dupont Circle, look for P Street, and head towards Georgetown on P Street.

You'll go across a bridge about four or five blocks. And it's the second left after you

get off the bridge. It's on 28th Street. And it's a very short block, and you'll get to 1406. It's a small townhouse. Just knock or the door will be open.

If you get off at Foggy Bottom, then just walk up Pennsylvania Avenue. But because 27th doesn't go through to M Street, you have to go up to 28th Street. That's why 28th Street is drawn.

And the corner of 28th and M is where the Ethiopian restaurant is, Zeb's. So those of you who are familiar with Georgetown, everybody knows where Zeb's is. So just look for Zeb's and then just walk up that street, which is 28th Street. Go up I think three-four short blocks and take a right on O Street. Then that will get you to the corner of 27th and O, and that's where the townhouse is.

Any questions about that? I put the phone number just in case somebody gets waylaid somewhere. And, as I say, we can sort of figure out where people want to go when we get there or people will break up within their groups.

I need to have an idea. I have probably a couple of cases of beer and also some wine that is chilling, et cetera. Right now I just want to

make sure I have enough. So I just need sort of an idea as to who might come. I just want to take a quick head count.

(Whereupon, there was a show of hands.)

PRESIDING OFFICER LaFORCE: That's not going to be a problem at all. Please.

COL DINIEGA: The people going, did you get a map? Did all of the people going get a map?

PRESIDING OFFICER LaFORCE: Yes, all of those people who are going over. And if you're not sure, just show up. You know, I believe in the African axiom. You've got food for ten. You have food for 20.

DR. SOKAS: And the red line is close to here. It's the Forest Glen station. So it's easy.

PRESIDING OFFICER LaFORCE: Yes, the red line is pretty easy.

DR. SOKAS: Right.

PRESIDING OFFICER LaFORCE: Okay. Thank you. I'm sorry. I took some of your time. You have plenty of time. Don't worry.

BW SYNDROMIC SURVEILLANCE:

REPORT OF A GEIS WORKSHOP

MAJ PAVLIN: I'm Major Julie Pavlin. I work here at WRAIR in the Division of Preventive

Medicine and also with the DOD Global Emerging Infections System.

How many people have heard my ESSENCE talk before?

(Whereupon, there was a show of hands.)

MAJ PAVLIN: Okay. Just a few. Okay. So I think Colonel Diniega mentioned this at the last AFEB meeting, that they would kind of like to hear a little bit about that. And then I'll finish up with some information on a meeting we had in May with a bunch of different people trying to pull together some ideas and a consensus on what we should be doing in terms of the health indicator surveillance.

I think due to time, I won't go through every single slide in detail, but you do have a handout that has them all.

Go ahead. Next slide. This is a lot of work, actually, that was originally started last year. So I give him credit, Major Mike Lewis is a resident, PM resident, here who did most of the beginning work on this.

Next slide. This is what I tell people when I'm all out at all of these civilian meetings, that we're in the military. So we have to have an

acronym. And this is our acronym.

Colonel Kelly made this up. I think it really says what we're trying to do. We're trying to find the health of a community or the disease of a community using some novel forms. And this is one way of using just syndromic disease information versus very specific types of disease information to get some of these things, to get more quickly to know that there is something going on in your community, to localize it, and to be able to get the word out to the people who need to know.

Next slide. So what we have in the military is something that they don't have in a lot of places in civilian, although they do in some HMOs. This is what we call a standard ambulatory data record.

The military started this some years back and actually consolidated all of them from all three services into one location approximately two years ago, two or three years ago, now.

What happens when anybody comes in in the military for any outpatient visit, whether it's the podiatrist or it's infectious disease or it's the orthopedic surgeon, any outpatient visit, they have one of these records filled out. And all of

this stuff you can't read, and it's not important.

This list right here every clinic picks -- and this is part of the problem -- their own 40, their top 40, of what they see. They can handwrite ones in as well, but I imagine that doesn't happen very often.

And so if you look at an emergency room or you look at a primary care and acute care clinic, they're going to have things like diarrhea on there or acute respiratory infection, very general, nonspecific symptoms. And these are all linked to ICD-9. The numbers along here are ICD-9 codes.

So all of these, every single person who comes in and has all of their identifying data, their age, their rank, their address, everything on there gets one of these things filled out when they first come in.

Next slide. And what happens to it is it gets scanned. And, actually, they're going to a more automated system. About 50 percent now of the National Capital Region have this automated system where it's entered directly into a computer. The rest of the people they scan them sometimes four times a day. At a minimum, they're supposed to

scan them at least once a day. So the military treatment facility gets these, scans these in. And it goes to a central database, which is in Denver.

Now, we have been able to get this data. Usually they take it. They compile it. The bean counters use it to determine how many kinds of physicians or equipment or nurses they need in that certain clinic.

So they take it, and it takes two or three months to make it look pretty and nice. And they send it out in nice reports, but we have been able to get it on a daily basis. So Monday through Friday, as the data comes in to them, they send it on to us as it happens.

So we don't have that many people, and we don't work weekends yet. Well, we do, but we don't. So we get it Monday through Friday. And we actually don't have a good enough fire wall here at WRAIR. So our person has to go up to Rockville at the Retrovirology Division up there and get it through their computer system.

Next slide. So this is the area we're looking at right now just as a pilot project. This is 104 clinics in a 50-mile radius of Washington, D.C. in 22 different geographic locations.

Next slide. The ones we have picked are the ones that you would expect outbreaks to originally present at. So it's the primary care clinics. And you can see the percent and the number.

Next slide. And we're using tri-service again. We have all services' data. These are just kind of reflective of what we see in the national capital region.

Next slide. And this is what we're doing. If we looked at every individual ICD-9 code, it would be very difficult to get to determine if any kind of syndrome is occurring. So, instead, we've grouped them into eight different categories, very general categories, such as respiratory, gastrointestinal, neurologic, fever, that kind of thing, so that we can take a look. But we do have the ability to break it back out should we see a spike or an unusual occurrence. We could break it back out and determine what exactly is causing the changes.

Next slide. So this is what you get. This is a couple of years of data that when we first got it, we plotted it out. This is for respiratory data that came into our clinic. And

you can pick out some of the Christmas holidays, but that's about it. It doesn't look very good.

Next slide. But if you break it out a little bit to just a month's worth of data, you start to see a characteristic pattern. And you see the troughs during the weekends and see the peaks during the weekdays. And you see a three-day weekend right here. It's a Saturday, Sunday, Monday. So you didn't get that. You see a secondary peak on Fridays. So you start to get some trends witnessed here. And those are all of the different categories there.

Next slide. So what we're able to do is to start to track this and see: What does it look like? So this is a combination of upper and lower respiratory data over the flu season this year compared to the flu season last year.

And everybody remembers all the hype this year about how bad the flu season was. And, in retrospect, it turned out that it was a little bit earlier than expected, a little earlier than it appeared than the previous two or three years. So it kind of took people off guard. It happened during the Christmas holidays. So people were out of work. So it made it a little bit more acute.

As you can see here, this is this year's with the kind of the little diamonds on here. You can see it really didn't get that much higher at all and probably the area under the curve is even less than what we saw last year and a little bit higher in terms of what we considered our lower respiratory.

But generally it wasn't that unusual. And we were able to determine this. The CDC certainly has their surveillance system going and was able to see that this was no different than it was in previous years in terms of numbers. We were actually able to track this as it happened, and we did track it as it happened.

Next slide. And you can see -- also I told you we could break it out. This is what we saw in the national capital region for what those ICD-9 codes were. This is during the flu season December through February.

And you can see most of them, again, they have these very generic ICD-9 codes. A lot of people think you can't use ICD-9 codes because they're specific, but there's a whole heck of a lot of them that are not specific at all.

This is URI, otherwise specified. This

light purple one is pharyngitis. I'd ask for adenovirus because we were looking at another location. You see very, very few, actually, said influenza because they didn't know whether it was influenza or not. That was upper respiratory infection. This one is viral infection not otherwise specific.

Next slide. This is also something we're doing. This is in conjunction with CHPPM. Mubums was a geographer up at CHPPM. And he is able to get the data from us and plot it in the D.C. area.

The background is the density of beneficiaries, which is now we can't do rates because how many of our beneficiaries are getting seen on the outside. We don't know. But this is just to give you a general idea of what the beneficiary population is. Then we can track by number of cases a certain disease over a period of however many days we want so you can see if there is any clustering.

Next slide. So certainly we have some problems yet that we're trying to work through. One is to need to define what the normal levels are and when do you get concerned and what do you do.

Next slide. This is taking that same flu data. This is upper and lower respiratory infections. One thought that Colonel Kelly had is to look at standard deviations from previous years.

So this is just looking at 1999 data and doing an average of a plus two and three standard deviations, above and below. But this is not just taking Monday, Tuesday, Wednesday. This is taking one Monday, three Mondays before that, three Mondays after that, and averaging those seven Mondays same day next Tuesday.

So it gives you the day of the week plus some seasonality. It's not just taking every Tuesday around all year long. It's just Tuesdays in February-March or in the January-February region. So this is looking at what you would expect to see on this Monday, Tuesday, Wednesdays, and so on and kind of matching them up to the following year.

And so this is the actual data. The red line is what we saw. And the blue and the green lines are those standard deviations. So you can see just with one year of data. And this is where we need more data. We do actually have -- we don't. We're getting it right now from TRICARE

Management Agency, '98 data as well. We actually did exceed those in the beginning a few times.

Next slide. You can see as our flu season waned, we certainly were very far below -- next slide -- of what you would expect. So you can see that they do follow pretty closely. So this is just a very simple way. We explored things like neuromed analysis in some very complicated ways, but this is actually a very simple way to look at it and see if anything is abnormal.

Next slide. So the next thing that we need to do is certainly sequelae. Everybody says, "Okay. Great. You get this data. It's probably crap because people just fill in anything they want." And, in fact, we did pick up one spike in fevers at our Naval Medical Center.

Our person, Christina Polyak, who looks at our data every day, noticed this spike. She called them up. And it turns out someone we knew was working in the clinic. So he was just filling in the top bubble for everybody. He thought that was easier.

They were actually really thrilled, I think. At first they were a little taken aback. Then they were thrilled that someone was looking at

this. You mean someone looks at this data? We can't believe it. I mean, we just thought you cared how many people we saw. We didn't think anyone really cared.

So I think if we get a little bit of feedback to these people, they will be a little bit better in filling it out. In general, you could see we did track flu data. So there is some kind of quality going on.

Next slide. This is an example. Everyone remembers the adenovirus outbreak at Fort Benning we had earlier this year. It was a big outbreak. I said: Oh, let's look at that data. Maybe we can analyze it. Maybe we can see: When will we pick it up and when did that turn out?

So we get the data. This is some seven-day running averages and all the spikes in there for respiratory infection. We're looking. Where is its peak? Is it here? Is it here?

Next slide. Next slide. It's there. Okay. So we wonder: What happened? Well, what happened is they were so overwhelmed that they stopped filling out the forms. So when they were hitting this peak, which, actually, when you look, it is pretty high. So it was going up there. They

just stopped filling out the forms.

So you might say, "Well, you could have detected it. Maybe you could have detected it here." It's too late. Obviously by this time, you don't have to tell these people that they've got an outbreak. They can tell you they've got an outbreak.

Next slide. But it's important to remember that not only do we want to be able to detect the outbreak, but, then, the second part of this type of system is to be able to localize it more quickly without having to go back and do a records review, without having to do all that shoe leather epidemiology. We might already have addresses and information and location already in there, and we didn't have it in this case.

Next slide. So there's some validating.

Next slide. This is just an example. We started out with a much broader use of ICD-9 codes. Then we got together in a group -- Colonel Keefe in the back was part of this group -- to look at them and say: Do we really want to include this or that? And so we took a bunch out.

It looks about the same a little bit, just lower levels. You see a little bit of

difference in here, and that's the allergy season. We took out a lot for allergic rhinitis kind of diagnoses. Appropriately, that's where we were seeing them, was in the spring. And that's people were not using those, I don't think, for other types of infectious outbreaks.

Next slide. So there are other things that we need to work on. Obviously we don't know about the -- I mentioned before the non-TRICARE population of people who are being seen in the civilian side.

Timeliness. They're supposed to. I said they're supposed to scan these every day in some of the smaller areas. Sometimes they don't scan them every day, and we have a little bit of a lag. So we might get the data. It says we have the data, all of the data, for Friday, but Monday and Tuesday is still trickling in.

Certainly we have to find a home and a right place for this. This is not going to detect everything. Large outbreaks, you're going to know it before we do, very, very onesies and twosies.

West Nile virus. I don't think we would have picked that up, although if it was maybe with -- especially something unusual, like a

neurological type of pattern, maybe we would have but have to find the right place and what this is actually going to work for.

Next slide. One way that we would like to proceed -- and, actually, if there is any way that the AFEB can assist us, it is in pushing forward this program.

Last year I had a budget of zero. We spent no money on this. This was all kind of done in-house, good graces of people of the CHPPM, good graces of people at TRICARE management. Recently I met with TRICARE management. They would like $220,000 to pay someone to do this for us and stop doing it just on an ad hoc basis. The CHPPM would like some money to reimburse them for their time.

And it's appropriate. It's highly appropriate. But we don't have that kind of money. So I really need to go to Health Affairs and say: Help us out here. Make this a priority in some of these other locations. Either fund them or remove some of their other priorities if you think that this is going to be a good system that will work.

The other thing is to work together. Obviously by ourselves, we're not going to have that much data, but it's work with civilians. I

have a lot of meetings and a lot of tentacles out with different health departments to try to merge our data with their data and make a more robust system as well as getting some other data, such as pharmacy and laboratory test data that we have, again, currently the military system through CHCS. So we're working on getting that right now.

Next slide. In an attempt to get working with some of the local civilian populations and to kind of move this whole idea of health indicator data forward, we have recently had a meeting -- this was in May; I think Colonel Diniega was there -- that we had up in Gaithersburg to talk about what -- because there are a lot of people doing a lot of different things. So to bring together some of those people, what works, what doesn't work, an what should we do in the future.

Next slide. So, again, these are our objectives.

Next slide. And we had a lot of different people from a lot of different directions. We had DOD people, people from USAMRIID, and then also some of the U.K. people, who are working on a lot of different similar systems.

And then we had, again, a lot of people from the local area, a lot of representatives from the health departments, from academia in the area that assisted us in what they were doing and what they would like to see done.

Next slide. In lieu of time, I won't go through all of these different issues, just highlight a few important ones as we go through. One is that there are a lot of different data sources out there. "What can we use? How do we access that data? How do we maintain privacy of that data?" were some of the biggest topics.

Next slide. Again, we felt that the privacy issues were some of the most important as well as trying to find data that was going to be more rapid, as opposed to more specific.

Next slide. Again, this is a big thing. We are lucky in the military that we have this system, but you know that the civilian systems are collecting this data. We know that they are somewhere. It is usually for billing and insurance purposes.

Sometimes it lags and it is very slow, but sometimes it's very rapid. They may not get paid that rapidly, but they probably generate a lot

of this stuff. So if we can tie into that and find that data and merge it together, it would be very helpful.

Next slide. Again, an ability to share information and the reporting. People need to see it in a local level, but it also needs to be able to be shared on more of a common ground as you go up the hierarchy.

Next slide. Okay. Next slide. Next slide. Okay. So, in conclusion, here obviously we're DOD GEIS. We can't make policy for the United States. We're not trying to. We're just trying to share what we have and try to work with other people and to give us some information.

After the CDC ICD ID conference in Atlanta a few months ago, I had a lot of people, probably at least 40 or 50 people, from health departments wanting just our list of ICD-9 codes that we use so that they could get an idea and start maybe working on those as well. So I shared that information, and we're certainly willing to share more.

Right now we're putting together a paper, hopefully have a draft done next month, for publication based on this workshop to try to at

least get some ideas out there in the peer review press so that people can start to work, maybe off a similar sheet of music, if not the same one.

I think that's it. Any questions? Discussion?

DISCUSSION

PRESIDING OFFICER LaFORCE: One question is: How connected are you with either the City of Washington or Prince George's County or the county health departments? Is this linked at all?

MAJ PAVLIN: It's not linked yet. Actually, they don't have the data. We are willing to just give them our sanitized in terms of privacy information data.

Actually, I'm working very closely with the epidemiologist from Prince William County, who is the consultant to the COG, the District of Columbia Council of Governments. I've spoken to their group, and he's their medical adviser.

And so we're trying to work with them in developing a global system. The problem is that they don't have any data at all, really, on this kind of rapid basis.

PRESIDING OFFICER LaFORCE: I thought if you're a big insurance company, that you're looking

at daily billings. Aren't these the same data?

MAJ PAVLIN: Yes. And, actually, another group we're working with at Johns Hopkins Applied Physics Lab had looked at data in Maryland, that exact kind of data.

They said about half of it was really slow, useless, two to three weeks. They said the other half was daily, right on target. And the problem is getting them to share and not so much privacy information in terms of people's identity but just their kind of business.

We have also gotten data, they have gotten data from major pharmaceutical companies that they couldn't even tell me what they were. They couldn't tell me what they were because these pharmaceutical companies, these major chains, would not allow them to give this information to anybody because people can look and see what their sales are. So there are a lot of business-government issues.

Some of the bigger labs that APL has looked at to get information, like Quest, wanted a lot of money to hand over that data. And so that's another problem.

MR. RUBERTONE: Julie, as this grows

beyond the DOD and into other organizations, what becomes of the responsibility for taking action at certain thresholds or is that just to provide the data so that it's available so whoever wants to look at it can take action?

MAJ PAVLIN: That was Mark Rubertone asking about response issues. One of my big questions right now is: Who is going to end up with this?

I don't think this should be a GEIS program. I think it should be owned locally either by each service so they can look at what is going on in their service kind of globally as well as locally in all of these different regions in San Diego, San Antonio, or whatever, so they can figure out what's going on and they can then write what their response that pertains to their particular area will be.

But that's a big thing. If you find out there's something going on, what do you do? Right now we're just trying to get a list of all of the people in the D.C. area. If I see a blip, the first thing I'm going to do is find out: Did someone just fill in the top bubble on the sheet? So who do I call, even, to find that out?

Colonel Diniega?

COL DINIEGA: I'm sorry. I had to step out, but I was at the workshop, which was very good. There were numerous systems presented. And they're all in the testing stage and pilot programs. I think this is a very, very important issue, syndromic surveillance, because most of the people on the hardware side that have testified will tell you they can't make enough vectors. And sometimes it's dependent on atmospheric conditions and upwind/downwind, et cetera.

So there's a lot of recognition from the operators that maybe medical surveillance is going to be the first way to detect an event. I know the medical community for years now -- and I have been working the bio/chem arena from the operational point of view for several years. We have always said medical surveillance is one of the added weapons they needed to have in their repertoire.

Really, I went to meetings knowing that we didn't have a good system, nobody was working on it, et cetera, et cetera. And the line has actually picked up on that, that surveillance, medical surveillance, is one of the other ways to look at detecting an event.

The shortage of funds that you heard Major Pavlin say is I think because, as has happened, we have checked this on, again, the medical side only. And then the other piece is the operators are more interested in medical surveillance during deployments, and we haven't solved that piece yet.

This is a first step. And with a domestic response, responsibilities that we all have, I think this is a step in the right direction. We just need to make sure that the rest of the community interested in the bio/chem response hear about what's going on with this medical surveillance piece so they can get appropriate support.

A lot of the system, it's like something in a vaccine. It still has to be tested and validated and looked at, et cetera. So I think there is a lot of promise and we just need it to get in the right place.

The Board two years ago in the BW threat review had a statement in there about the importance of medical surveillance to identify threats. That's one of the reasons I wanted Major Pavlin to be able to present what was happening and

the results of the workshop to the AFEB.

So this is part of the response to some of the recommendations the Board made several years ago.

PRESIDING OFFICER LaFORCE: Okay. Thank you.

Captain Bohnker, we have a presentation on microbial-based cleaners, which relates to a question to the Board.

COL DINIEGA: Right. I have a copy of the question. The Navy Surgeon General endorsed the request, and I have the handouts here. What they'd like the Board to do is to review and comment on a draft set of draft criteria that the Navy Epidemiology Board and NEHC has put together to conduct a health hazards assessment of microbial-based cleaners. And you'll hear the rest of the story from Captain Bohnker.

It's all yours.

CAPT BOHNKER: It's all mine?

COL DINIEGA: All yours.

MICROBIAL-BASED CLEANERS

CAPT BOHNKER: I'm Captain Bohnker. I'm from the Navy Environmental Health Center. Dr. John Muller back there, a gentleman appropriately

camouflaged back there, is my compatriot in crime. We're up here today to talk about some issues that came across our desk.

Next slide, please. The topic is "Microbial-Based Cleaners: Background." The Navy Environmental Health Center has a process to assess the health hazards associated with shipboard materials, a pretty big process, all the way from submarines, aircraft carriers, a lot of issues right there.

Historically it's been a toxicity assessment, shipboard industrial repair activities. You get in topics with the Cursed a month ago. We were involved with that. We get in processes like that.

Recently we have requests to use a microbial cleaner in a shipboard environment as a substitute to reduce volatile organic compounds, VOCs.

Next slide, please. Great PR piece. This actually came from the business cards for these people. The stuff is called Nature's Way. It's made by American Bio-Clean Corporation in Las Vegas, Nevada. The agent is Donald E. Wantz, Master Gunnery Sergeant, United States Marine

Corps, retired. It's his expertise.

It's proprietary contents. It's on the card, "The simple, safe parts-washing technologies." It's cleaner for aviation guns and alternative PD-680 on the aircraft carrier. The actual reason was it had to do with some air conditioning spaces that they couldn't use on the ship also.

Next slide, please. Interactive review of the issue, did a chemical toxicity, which is relatively easy to address, at least for the nascent products.

That was pretty simple. We thought we could do that. This was biological stuff. This wasn't a chemical. This was a biological. It's a bunch of bugs in there. And the biological pathogenicity was much more difficult.

Minimal guidance or precedent. There's an awful lot of toxic products. You get into a whole gamut, a minimum amount of bay, toxic shock. I mean, you can go anywhere, going, "What's in it?" Can't know. It's clean, safe. It's approved for use in California is about all they'll tell you. The Navy Epidemiology Board reviewed it in June of 2000 and recommended we let you all take a

look at it.

Next slide, please. What about opportunist infection, diagnosis, treatment, antibiotic-resistant, irritants, allergen effects, genetic movement, byproducts, and more?

Next slide, please. Our question to you. We're requesting you, we've come up with a two-page list of some questions we'd like to have answered from this, people. And we'd like to have AFEB take a look at it, see if we're missing anything because it's one of those completely out of our ball game down at the end, one of those we don't quite know what to do with this.

It's an issue throughout DOD. We've seen some paper from CHPPM on using simpler products. Consistent guidance is warranted. We'd like you to review and promote comments on our draft information. It's new, and it's big. When I say the name "Nature's Way," everybody says, "It's great stuff. Why don't you use it?"

I go, "Hmmm. The stuff scares me." So I don't know what to do about it.

Next slide, please. And we thank you for your advice down there. Are there any questions from the group?

DISCUSSION

PRESIDING OFFICER LaFORCE: What is it? What is it?

CAPT BOHNKER: What is it? Nature's Way. It's a biological --

PRESIDING OFFICER LaFORCE: You mean it's a bunch of bugs inside of something that clean things up?

CAPT BOHNKER: Yes.

PRESIDING OFFICER LaFORCE: And so if you want to clean a gun, you just put that stuff down there?

CAPT BOHNKER: Yes.

PRESIDING OFFICER LaFORCE: And then you just flush it out, and it's all cleaned?

CAPT BOHNKER: That's the theory, yes.

PRESIDING OFFICER LaFORCE: Good. I just wanted to make sure I understood. Okay. Ken, help us out.

CAPT SCHOR: I sat on the Navy Epidemiology Board also during these months. It was a little bit out of my ballpark, too, but my understanding of this is that in a lot of statements of the DOD, the Marine Corps, and the Navy, there are a lot of product reps that are

pushing these kinds of cleaners. They sound like they're the green answer to all this nasty stuff, all of these solvents that we're using to get rid of heavy-duty grease and corrosion and things like that.

My understanding of this is that there's not a whole lot of legislation or regulatory parameters, at least from the toxicologists and folks like that, that specify how you characterize the biological component of it.

DR. OSTROFF: What about the EPA? I mean, presumably if this is being marketed, the EPA has regulatory authority over it.

CAPT SCHOR: I don't think that they're even -- the way it was told to us is they could find no one in government, a physician, medical toxicologist, can't find any regulations to govern this whole arena of emerging biologically active compounds.

DR. OSTROFF: Do you know if they contacted EPA?

CAPT SCHOR: I do not know. Maybe --

CAPT BOHNKER: I'll check on that.

DR. SOKAS: Actually, there is one committee that's OSHA, NIOSH, EPA that meets

periodically. And it's the kind of thing that could get on their agenda.

You would have to be able to tell them more than this. Do you know what I mean? I mean somebody has to know what bugs they are, for example.

COL GARDNER: It's unclear to me -- it talks about in the product these are enzymes of the organisms -- whether they're actually the organisms themselves. They talk about a combination of enzymes and bacteria. These are live bacteria?

CAPT SCHOR: Yes.

COL GARDNER: I don't see how this Committee can begin to make a recommendation if it doesn't know what the bacteria is.

CAPT SCHOR: See, I think this is part of the Navy has evaluated chemicals that it uses in shipboard environments or operational environments. And that's where the expertise is.

My understanding is either you throw it in a mass spec and figure out what's in it if they won't tell you or they tell you. And I guess we're running into an arena where the producers of these things won't tell you and it's pretty hard to figure out what it is by throwing it in an

analytical machine.

DR. SOKAS: I mean, there is a right-to-know law for workers that you cannot have them working with something without letting them know what it is and what it can cause.

So it just seems to me that they might have slipped by a few little regulatory things but that -- you know, actually I like the idea of setting specification for purchasing products. I mean, that's a great idea in general. But it would seem that it's just kind of missing a step, which is the first spec is you've got to tell us what's in it.

CAPT BOHNKER: I think the question to AFEB was to look at that sheet of paper and see if the Navy is missing anything. That was the real question.

DR. SOKAS: Well, what's in it? That would be the first question.

COL DINIEGA: Let me just say that I talked to Captain Betts, who sits on the Joint Environmental Surveillance Working Group, which Captain Schor and myself also sit on there. This came up several meetings ago.

I think what we and the Navy Epi Board

did was put together a draft criteria in order to evaluate this product so that there can be a right decision or a justified decision to say "Yea" or "Nay," we're going to use it or not and purchase it because the industrial-based operations all want to buy it. So it was their attempt to put down performance criteria of questions they need to ask, so specifications on a product.

So we're not talking about a specific product here. We're talking about generically because more and more of these green or microbial-based or enzyme-based cleaners are beginning to be advertised all over the place.

My understanding from Captain Betts was there was very little regulatory action. They weren't required to conform to anything that he could find out from it. And Captain Betts is a very meticulous guy.

So that's why. They just want the Board to review the performance criteria and see if those make sense and if they're missing anything.

Now, did they do their homework and ask the EPA, et cetera, et cetera? I just assume that they did, but they can go back and do it. But they're just asking to take a look at the

performance criteria.

PRESIDING OFFICER LaFORCE: Julian and then --

DR. HAYWOOD: It says that "The Navy Environmental Health Center has been requested to perform a health hazard assessment." Has that been done?

CAPT SCHOR: No. This is what they would like to use as their criteria for performing the health hazard assessment. Is that right?

CAPT BOHNKER: Yes. We have not done one because we don't have the criteria.

CAPT SCHOR: So they're trying to come up with evaluation criteria.

PRESIDING OFFICER LaFORCE: Linda and Rosemary.

DR. ALEXANDER: Isn't it a job for the Consumer Products Safety Council?

COL DINIEGA: I don't know. I don't know.

DR. ALEXANDER: I mean, my understanding is that their purview is to evaluate products that are used by consumers. It would appear the DOD is a consumer and that this would be a reasonable request to take to them for evaluation. Then the

ball's in their court to figure out what it is.

It's hard to believe that someone who eagerly wants to sell DOD something is not willing at some point to talk about what it is. If we're dumb enough to buy it, that's our problem, but this just seems like an exercise in futility.

DR. SOKAS: Well, I do think, though, that the idea of having these kinds of performance criteria is an excellent one because already what you have here is probably far and away beyond what EPA or the Consumer Products Safety Commission or anybody else would be asking for.

So this is useful and very valuable supplemental, but there does seem to be a need for a core something there as well.

DR. ALEXANDER: Something's missing.

COL SMITH: When I was at CHPPM, we looked at another product very similar to this called ZYMO. The name may sound familiar to you. It is very difficult, very difficult, to get information on the constituents.

The ZYMO, which this may just be the same thing renamed -- I have no inkling. I think it's the same name of the person who is selling it. Nevertheless, the ZYMO was a mixture of enzymes,

of some sort of enzymes, plus several bacteria. And we couldn't get much more information than that.

What little health hazard assessment we could give was simply recommendations to protect workers that were generic, like make sure you wear gloves. X percent of people are likely to become sensitized to these proteins.

But we couldn't get very specific because we had the same problem. We couldn't get any specifics on that. We tried. Larry Betts tried to get us to get the doors opened, too, and we couldn't.

DR. HAYWOOD: Can't the manufacturer conduct a health hazard assessment?

PRESIDING OFFICER LaFORCE: We have no way of knowing. One question that I have in all of this, this stuff I'm making the assumption really works and works well and you like it.

CAPT BOHNKER: I can't answer that statement. There are some people who would very much like to use it in the military, yes. It has some --

PRESIDING OFFICER LaFORCE: That doesn't answer my question. There may be other reasons why

they want to use it. I'm just asking the question: If I've got a dirty gun and I use this stuff, does this stuff do a better job than the other stuff that I've got around? In other words, is this really of value to the military?

CAPT BOHNKER: The reason it was brought up was the fact that it gets into aircraft carrier spaces. The chemicals they were using, the PD-680, was causing some other toxicities they can get rid of. And it made the life easier for them to do some things they wanted to do in terms of habitability, shipboard air condition spaces, less toxicity from volatile organic chemistry or compounds was what it was. It was as effective and not as toxic. And so they wanted to use it.

DR. BERG: So the weapons operators have used this to clean weapons, and they like it?

CAPT BOHNKER: There was strong interest from them. I can't say they were happy with it.

DR. BERG: You don't know whether they have ever taken any of the stuff on board and poured it on the greasy guns and --

CAPT BOHNKER: I believe it works. I mean, I don't think that -- people are trying to sell it. It worked at some level.

COL SMITH: We do use this same technology.

PRESIDING OFFICER LaFORCE: Oh, yes. Oh, yes.

COL SMITH: We know that there are, in fact, materials that work.

PRESIDING OFFICER LaFORCE: Okay. Rosemary?

DR. BERG: What occurred to me is this may work, but how long doe sit take?

COL SMITH: Well, one of the other problems with the particular cleaner that I looked at is temperature, the temperature you have to maintain it at. It has to be at a certain temperature, which we were concerned about aerosolization of it and breathing it in. At the temperature it had to be maintained, it couldn't have been a --

PRESIDING OFFICER LaFORCE: Rosemary?

DR. SOKAS: Just, again, to get back to the list, I think it's a terrific list, but one of the concerns is: How do you know their answers are true? Do you know what I'm saying?

They could say, "What is your data from medical surveillance programs from human use and

response to the product?" And they could tell you anything they want, basically.

It's just if you're dealing -- I don't know how much you would trust the responses if that's all you have to go on is what people are -- I mean, you do have to have some externally validated piece of information.

And in other circumstances, you have federal agencies. For example, for new medications coming online, somebody looks at that. And there are agencies with responsibility for looking at this. And I think, again, there probably is a need to see if they're paying attention because they may not be.

PRESIDING OFFICER LaFORCE: Actually, when I think of this as an intellectual challenge, it's actually sort of interesting. I mean, this is the future from an environmentalist's standpoint.

Also, if you're looking at stuff downstream, this is likely to be more common, rather than less common, as time goes on. And it's a very interesting sort of biologic medical question, you know, this whole issue.

And, two, how do you sort of wrestle with this? I'm not sure I have any acute

intellectual insight.

DR. MUSIC: I believe this is sold in interstate commerce. It comes under somebody's jurisdiction. And the proprietary things have to be protected so that they can market it.

I don't think anybody has really asked the right agency, but somewhere along the line, it's got to be under somebody's regulatory thumb.

PRESIDING OFFICER LaFORCE: I can't think out of the miles of regulations that we have, that we managed to be so clumsy as to have left this out.

DR. SOKAS: And the other thing, though, is that once we figure out who it is that's regulating this, this list of questions would be very informative to find out if the regulators have, in fact, included this kind of criteria.

PRESIDING OFFICER LaFORCE: Okay. We will think deeply --

CAPT BOHNKER: Dr. Muller has one more comment.

PRESIDING OFFICER LaFORCE: Yes?

DR. MULLER: One of the problems when we looked at this was that we couldn't find out where it was regulated. I'm pretty sure Captain Best did

contact the EPA or a friend of his in the EPA. And if you look at toxic chemicals, chemically it's okay.

As far as biologicals, it's not like an endangered species, like a tiger or something. So it gets out of the -- if you look at the various parameters, it kind of skirts a whole bunch of issues.

And you have someone saying it's really good. Trust me, like, well, we're kind of not inclined to do that. And so we're trying to figure out criteria. Well, what hoops does this have to go through?

DR. SOKAS: You know what? I really feel like this is something that NIOSH ought to get a little more engaged with. So maybe if we can try something, we can try to figure out if there's some approach to this that is or should be being taken. If that's a complete hole in the regulations, then this might be the place to identify it.

PRESIDING OFFICER LaFORCE: And if you could identify the company so that members of the Board who wish to invest in it can be sure to get in on the ground floor?

(Laughter.)

DR. MULLER: They showed us some slides of this product working. I wasn't impressed with how clean it got, the screws or whatever they were working on, but something strange was that it supposedly cleaned in like two minutes.

We were all like, "Nah. These are little bugs munching. It's going to take longer than that." So it made us really wonder. Is it enzymes? That's a chemical. What really is this? And we got no answers. And so I think to be fair, we wanted to know what criteria can we have to be sure we're not --

PRESIDING OFFICER LaFORCE: Has anybody cultured it?

DR. HAYWOOD: They keep on cleaning after it's clean?

(Laughter.)

DR. MULLER: We have a concern, like: What if it gets into aircraft fuel? If these bugs get into gasoline and the F-18 takes any of those to Madrid, that's not so good. All of that is I think reasonable questions to ask.

PRESIDING OFFICER LaFORCE: Has anybody cultured just simply taken a swab and put it on a blood auger plate or a --

DR. HAYWOOD: I walk down these corridors, and I can't believe --

PRESIDING OFFICER LaFORCE: I'm just curious.

DR. HAYWOOD: -- there's no laboratory in this building that just read it for this present.

PRESIDING OFFICER LaFORCE: Bill?

DR. BERG: Bill Berg.

There are at least two starting points, potential starting points. The outfits that make the bacteria for eating the oil slicks, there might be something analogous there to this and then those things that you can buy for washing your clothes, the little enzyme sticks and liquids that you pour on the stain, which I guess would come under consumer products.

Taking this to those groups, they might say, "Yes, this is close enough to come under our regulations." But I like the idea of NIOSH looking at it also.

PRESIDING OFFICER LaFORCE: The other thing is if it works in two minutes or less than two minutes and it is analogous at all with some of the cleaning enzyme preparations that do have a

biologic basis to them, then that's usually short term. I mean, it doesn't take minutes, hours, or whatever.

And so my sense as a biologist is it just doesn't make any sense at all in terms of thinking that this is a live organism doing anything.

COL GARDNER: Except they say it is bacteria. I mean, I'm thinking the sort of thing: Could this be a very wafted serratae? I'm thinking this is a totally innocuous organism and then it wasn't.

And the ability of organisms to accept plasmids or to spread plasmid, it seems to me there's a lot of --

PRESIDING OFFICER LaFORCE: But they are not going to grow in two minutes.

COL GARDNER: No.

PRESIDING OFFICER LaFORCE: Biologically this doesn't make any sense. It's an enzyme. That makes sense.

DR. MULLER: They're claiming it's bacteria.

PRESIDING OFFICER LaFORCE: Right. It could be a bacterial enzyme.

DR. MULLER: This isn't the only product that's come. There have been others. So it's like: Well, what mixture is your product? Is it mostly enzyme or is it just nothing but bacteria that --

COL GARDNER: It's got to be enzyme. The amount of biologic mischief you could envisage here would be enormous. And it seems to me we have to know a lot about it, including what it is.

COL DINIEGA: Well, you know, when I used to be on the Hospital Inspection Committee, in order for them to buy cleaning products to be used in a hospital, it had to be on an EPA-approved list.

So I don't know what the requirement is for industrial operations, if it has to be on some sort of an approved list or not, but I know in the hospital, it had to be on an approved list.

PRESIDING OFFICER LaFORCE: Anybody have any brilliant insights into this problem? Yes?

COL SMITH: Did they furnish you a material safety data sheet on this?

DR. MULLER: I think they did, but that was based on whatever the culture was, water with --

COL SMITH: They didn't say anything about hazards?

DR. MULLER: They told us very little. It was basically saying: This is safe. And I think they did give us an MSDS that didn't have much in it at all.

And our concern wasn't the toxicology of it. It wasn't that it was a poisonous cobra. It was that it was a tiger that wasn't poisonous, but it was still dangerous. That was our concern.

You know, the chemicals that were in it were not of concern. They were organisms that we didn't know where, who would regulate it, who has any information. And it seemed like it was a new area that was certainly worth looking at and a very large one, but no one seemed to have any guidelines for how to evaluate this.

PRESIDING OFFICER LaFORCE: We're going to talk about this tonight at my place.

COL SMITH: You know, when you say you're going to throw a gun in there and the fact that the metal will have -- lead or, you know, if they did bigger things like depleted uranium, you've got some concern about: Is this going to produce some sort of an organo-metallic compound?

That would be dangerous, too.

And I think everyone remembers Manama Bay. So I think some of these, no matter where the AFEB answers, someone needs to at least address it within the regulatory framework.

DR. ALEXANDER: Hollywood could have a heyday with this one.

COL SMITH: Oh, man.

PRESIDING OFFICER LaFORCE: I could just see the --

DR. ALEXANDER: Can't you see it?

PRESIDING OFFICER LaFORCE: -- opening session of the movie as this meeting.

DR. ALEXANDER: That's right. That's right.

(Laughter.)

PRESIDING OFFICER LaFORCE: Then Godzilla finishes.

DR. ALEXANDER: That's right.

PRESIDING OFFICER LaFORCE: Let's take a break for 15 minutes.

(Whereupon, the foregoing matter went off the record at 2:54 p.m. and went back on the record at 3:18 p.m.)

PRESIDING OFFICER LaFORCE: The next

topic on the agenda is the update of DOD ergonomics. This is a continuation of discussions that we had, I believe at our last meeting. Colonel Lopez, please.

COL DINIEGA: Colonel Lopez, you'll have to use the podium because we're recording the meeting.

UPDATE OF DOD ERGONOMICS

LTC LOPEZ: First of all, my name is Mary Lopez. I'm the Chair of the DOD Ergonomics Working Group. At the last meeting, I presented an overview of the working group activities in a very sketchy plan for our approach to a cost-benefit model.

I want to, first of all, thank the AFEB for their response to our questions and ask their permission. As we go through this presentation, you'll see that I continue to have questions. And, if possible, I would appreciate the opportunity to come back and provide a further update and dialogue with this Committee.

The first item on your response was about the DOD action plan, the DOD ergonomics action plan. What we have done in the interim since the last meeting is have Mr. Bowling, the

Assistant Deputy Under Secretary of Defense for Forest Protection, send a memorandum out to all of the services and agencies asking them for an update, the status of their ergonomics programs.

Particularly we want to know about any policy initiatives, how they have allocated resources, -- and our suspicion is they haven't allocated very many resources at all to this program -- what resources have been shifted to cover the program, how the program has been executed, if there have been any success stories, successful programs that have been implemented, what kind of oversight all the services provide to the program, if they have had any revisions at all to their policies, which we greatly doubt there have been any revisions, and then the five-year action plan.

On the back of the handout that Colonel Diniega has just passed out, you will see a copy of that memorandum that Mr. Bowling sent out to all of the services and agencies.

The deadline for that response is the 31st of October. And that will provide a lot of the basis for our continuing discussion in our working group for the action plan development.

At our November meeting, we will be talking about the responses to this survey. In particular, we want to target our efforts to develop policies among all the services. We do have the DODI 6055.1, but a lot of the services are slow in implementing a set policy.

For example, the Army just signed a headquarters GA letter, essentially an AR, for ergonomics programs. The Navy has a very sketchy program under their NAVOSH standard. And the Air Force just has a policy memorandum signed up from the surgeon. So we do want to target those service and agency policies.

We do want to pull together on our resource submissions. And the cost-benefit model that I will discuss in just a minute is going to be an important piece to our packages that we send for to the POM folks.

In terms of execution, we want to look at how we're pulling together to develop installation of other programs. From the Army side, we are conducting a base-by-base telephone survey to evaluate how far they are in the development process. I hope, I suspect, that the other services are doing similar data collection

efforts.

One of the things we do want to get are some success stories and best practices, which will not only serve for the developing programs but also serve to feed into the cost-benefit model, as you'll see in just a minute.

I know we do want to talk about oversight and what is the best mechanism to encourage an oversight in the Department of Defense. As I said, we have a meeting in November coming up. And if it's acceptable to the Board, I would like to be able to come back to the next meeting and give you a further update on how we are coming on our action plan.

So now to the cost-benefit model, which is really my focus over the last few months, which has been quite a challenge, just to give you a refresher, our target audiences are rather varied.

The first is the local Safety and Occupational Health personnel. We want to be able to give them an instrument, a tool, that they can use to go to their commanders and either justify their recommendations for some kind of design change or justify their existence, their program development efforts to their local commanders.

We also have to target resource managers. And as a piece of this, we're working with the economists, health economists, to make sure this is a valid and tight model.

We also want to target MACOM and the service and DOD decision-makers because ergonomics as a lot of injury prevention efforts have been met with some skepticism. And we're not high on the priority list a lot of the time, although we think we should be, but we're not.

Target uses. As I said, decision-making tool, design changes, and resource allocation. What we would like to see in the end is a tool that the local installation folks can go in through the Web, plug in some very basic inputs, and then get a cost-benefit analysis, output that, again, is solidly justified.

We'll start with the inputs. The inputs in the model to date -- and I'm very open to any suggestions you might have -- are, first of all, the service. The reason that we want to include the service is that there seem to be some differences in injury rates, even amongst similar jobs among the services, and the location category.

The location category is not only

important for the costing of the health impact or the hospitalization and ambulatory visit costs but also the magnitude of the physiologic stress or the activity in that particular location.

Now, this is where I'm running into a little bit of a problem because what we need to do in this model is keep it simple enough and broad enough that we still make it a useable tool but specific enough to have some value. What we need to do is be able to equate the MOS to the government service to the DOL SIC codes.

OSHA recently, as you probably know, has put out a proposed ergonomics standard. They conducted a pretty extensive cost-benefit analysis of this. What we would like to do is in the development process of our model pull in what work they have done because they had some pretty reasonable inputs and they pulled in a lot of experts in the development of their model. I will explain what they have done as I go through this process.

So we need to be able to equate all of these things. And, again, if you have any recommendations for me, I am very, very open to it.

What OSHA did is actually buy SIC code,

identify a hazard risk score based on case studies and expert opinion and expert judgment. From all I can see from their documentation, they did not go ahead and validate that with any field studies, but they did base it on their Department of Labor injury data.

Their focus really was on the general groups, the general populations, rather than individual interventions. Our model is looking at both. Remember, I said we wanted to address the program elements as well as the individual intervention; for example, redesigning a special work process or work flow in a warehouse.

The gender, age, status, and rank have been up for debate. We don't know if it's a necessary level of detailing or not. We do know that women have a greater risk of injury than men, but, again, when we start building the supporting data that feeds into this model, that database becomes large.

So people are looking at exactly what level of detail is required. And then, of course, the number exposed to that particular hazard, it might be by the base or by the job series. It depends on exactly what we're looking at.

The other imports are the task, tool, equipment, and system information. What we need to know is exposure frequency. Now, if I'm looking at a general population, I probably would not be as concerned about these particular items, but if I'm looking at a particular intervention, like, again, I want to redesign the work flow, I need to know how much of that time those people are exposed to that work flow.

For example, some people have looked at the design of the rucksack for the 11-Bravos. We know that that can cause back and shoulder problems. How often do they wear that rucksack? And how long are they exposed to that risk factor?

So that has to be built into the model as well as the type and the force, the repetition, and the other standard ergonomic factors that we captured, which will feed into the risk assessment code that I'll show you in just a second.

And, as I said, general population, the program level, I probably would not be interested in the exposure frequency and duration. I would more likely be looking at an overall risk level for that particular occupation series. But if I'm looking at a particular item, I want to know that

information.

Now, for the health outcome, this is another sticky point that we have run into. What we really need to do is relate the DOL nature of injury codes and ICD-9 codes and the VASRD codes. The NIOSH folks actually went ahead and went to the body part affected, which is part of the DOL nature of injury codes, but we are running into a bit of a concern with ICD-9 codes because if a patient is seen in a primary care clinic with back pain, they might just be given a general back pain-type diagnosis.

But as they go to a specialist for that episode of care, that diagnosis is going to change. So how do we track that over time to really collect information on that episode, rather than just individual clinic visits?

The other parts of the health outcome that we need to include are the severity and probability, the basic information that we include in the risk assessment codes. Again, it's a one to five or one to four scale.

Now, when you do that matrix, each one of those cells by the OSHA standard and by other models we have looked at has a weighting. For

example, if you have a high probability of injury and a very high severity of injury, you're going to have a very strong weighting in that cell.

The reason we are doing it this way is that if you take a factor from the hazard exposure things, the duration and the frequency, and multiply it by this weighting factor from the rest, then you will be able to get a better idea of the work-relatedness. And I'll talk about that in just a second.

Now, are there cost impacts? The next step actually is the cost elements in the model. I've talked about the inputs. Now we're going to talk about the cost elements.

There are various levels we can look at cost elements. For the short-term, the model really is looking at the impact on productivity and the profit. I put profit in parentheses because the military doesn't really have any profit motive, but we are concerned with productivity and deployability and all of the other factors we have always heard about as well as the health care system use, which is a little bit unusual from the civilian world because that health care system use is really our direct care delivery system, rather

than an insurance system.

These next items are standard things that you would include in the short-term, the productive hours, the salary of the people, the amount of training that has gone into that person, the length of time in the service, the turnover rate and productivity, and the soft quality losses.

The long-term impact actually is an insurance-type impact. And we see that with the VA system and the disability systems as well as the Worker's Comp system.

And then the unemployment state as they move out of that workforce, it's really a societal cost: the cost to the state; the individual; and, of course, society with that lost productivity.

Okay. Now, the health outcome. This ties back again to what I was talking about with relating the ICD-9 codes, the VASRD codes, and the nature of injury codes. We wanted to make sure that we put the appropriate level of detail without getting so far down in the weeds that the model itself, the construction of the model, becomes unwieldy for us to actually make it happen.

The standard cost, the health outcome cost elements, are seen here with the disability

from the military and the VA. We have the regular payments that we see on a monthly basis, again from the military and the VA, and then societal costs to the individual, which are softer costs.

And there have been some debates about actually including this in the model because this is not an out-of-pocket DOD cost. The current thinking is we can usually back it out or put it in depending on the user's preference, but this is a debatable item.

Okay. Hospitalization costs, not only hospitalization days but the lost productivity of that individual in convalescent leave, which doesn't seem to be captured as much as they used to capture as an inpatient day. And maybe Paul Amaroso can help me out with this one a little bit.

What we have looked at with the hospitalization costs are some DRG rates by region. And there is, again, some debate about the best way to approach that because there are standardized DRG rates across the United States which we can use or, again, they vary by region.

We have looked a lot at the Federal Register and the established third party payment rates. Again, there was a lot of debate about

which rate to use because there are some interest service rates as well as international rates. It seems like those lower rates are more out of good will, but the third party rates are the insurance payment rates, which seem like they're the most appropriate reflection of true costs of that hospitalization or that ambulatory care visit.

This has been a bit of a concern because there have been some service differences that we noticed. And I have an example from DMED that I will show you in just a second. We don't know if it's the actual rate differences or the amount of reporting that they're doing.

The Navy seems a little bit low, but I have heard that ADS isn't capturing information on ships. Maybe the Navy folks can verify that. Marine Corps, I would expect that they would have a rate that is closer to the Army, but theirs is also much lower.

The other problem we are looking at is the visits per injury and how to actually track that episode of care and how to define that episode of care as the diagnosis can change over time.

And then, of course, the lost productivity and the supervisor time, that's

related to the ambulatory visit. And when you stop back and think about it, if you're looking at an enlisted soldier, that lost productivity and supervisor time can be significant because, especially for the lower ranks of enlisted, they have to go to appointments but they also have to have a buddy who goes along with them. They usually spend a lot of time at those appointments waiting. And so you do have a significant productivity effect just by having a single clinic visit.

The other problem that we have is just basic health behaviors and decision-makers because there seems to be a gender difference on when they're going to seek care. Men tend to hold out longer before they actually seek care. Of course, the theory is that they're end case is more severe than the ones who seek care in the beginning.

So there are some differences on the decision when to seek care, but also the decision-makers, the practitioners themselves, because we have looked at differences in profiling. And with the recent low back pain clinical practice guideline, they started tracking profiled prescriptions among primary care physicians and

found a great disparity.

Some providers for exactly the same case, the same clinical presentation, were prescribing one week or two weeks of limited duty time. Some were prescribing up to four weeks or six weeks of limited duty time.

So there's a great disparity in exactly what the impact of that health condition is. And that, again, causes some problems with the amount of that variability.

Okay. Next slide. This is the DMED slide that I was talking about. You can see the red line is the Army. Air Force is blue. And you see a steady trend increase, which I assume is as ADS is collecting more information among the Air Force providers. But, of course, the argument between the services is that the Air Force has less physically demanding work. So maybe that gap isn't as surprising. The Marines, though, I would expect a closer trend to the Army. And then the Navy is the lowest line.

Next slide, please. Anyway, I typed out the rates so you could actually see what the numbers that follow that graph look like. And this was for all musculoskeletal disorders. I just did

a very broad-brush picture for all enlisted people.

COL SMITH: These are only these, though; correct? So a Marine would just tough it out?

LTC LOPEZ: Yes.

COL SMITH: Your answer is sort of skewed on the basis of --

CAPT SCHOR: Actually, it's the same problem in all of the naval services. We don't capture ADS data for 50 percent or more of the outpatient visits. Battalion aid stations, flight line aid stations don't have that bubble sheet that was shown by Dr. Pavlin before.

We're not linked in to CHCS. Hays, Gray, and underway ships don't use that. They just are lucky if we have something called SAMS that works half the time for us.

CDR MURPHY: To add on to what Captain Schor is talking about, we have talked about population health from the Navy. I include the Marine Corps in that. You're talking probably about 300,000 active duty members who do not have as their primary care manager somebody that's a claiming C-18 or Navy medicine.

They're being seen by medical folks that

belong to line Navy or line Marine Corps. So they're not using any of the structures that belong to Navy medicine for taking care of their military personnel. So that, then, is not being captured.

LTC LOPEZ: Well, going back to the original question, then, if this Board has any recommendations on how to capture that data or if we need to just fall back on expert judgment or some kind of estimation, what the best process to, again, reflect what really is happening would be greatly appreciated.

Limited duty. That's an obvious. Any time there is a profile written that you have some time lost from work, there's a percent productive. And that would play into the equation. So as with supervisor staff time, try and figure out exactly how to accommodate this particular profile in the work situation.

So, now, the next key point that I have come to is actually the work-relatedness of the condition. And most of the models that I have seen really have this as a pretty significant hole.

So I'd say: Okay. There have been X number of musculoskeletal conditions. How do I know that's really related to the work environment

versus especially for the military the sports activities, the civilians' predispositions, or some other factor in there?

The way we're trying to approach that is have it determined by the inputs using that frequency, the duration of exposure, and then the severity and probability of injury, which is a little bit tough, but, again, -- and I can see Colonel Smith making a face over there, but if you have a better answer, we're open to it.

I don't know of any good answer for this particular problem. We do want to make it solid enough so that we can stand on fairly firm ground when we go to resource managers and say, "This is the true ergo-related cost of these injuries."

Okay. Next slide, please. And, as I said, the problem that we run into is previous injuries. And that seems like that's a fairly good predictor of future injuries. The civilian employees with their off-duty activities are a predisposition to injuries. And with our aging workforce, we're running into more problems with this.

Military, the physical training seems to have a pretty significant impact. The problem that

I've always had with the physical training is that for the injury prevention initiatives, that's a clear target.

When you have somebody going out and doing X number of pushups and then they complain of wrist pain, you know, that's an obvious. But you're not taking the next step of looking at what the work activity is.

So that fellow does the pushups, and then he goes and lifts a 100-pound toolbox all day long as a mechanic. So now you're compounding that injury that already started with the pushups or maybe it started with a tool kit and then it was compounded by the pushups.

So how are you going to tease those two pieces apart? I honestly don't know if it's possible, but at least we could come perhaps down to some professional judgment.

And then, of course, with the military, we do have off-duty activities and a predisposition. And what we're finding with the troops that are coming into the military is that they are like porcelain soldiers, that they look very good, but they're easily broken when you put any kind of physiologic stress to them. So, again,

we're trying to look at whatever evidence we can so that we can come up with a fairly solid answer for the work that they do.

Now, the next element is the production effect. There are some elements of our working group that feel that this aspect of the work of the cost-benefit model is actually going to be stronger than any health outcome because you can go and you can change a job and redesign a job with a side benefit, as I've said before, of having a reduced injury rate. But you're going to see the greatest bang for your buck out of the redesign of the production side of it. And that also addresses line concerns and management concerns, and it's a better selling point.

These are just basic activity-based costing processes to look at a current design and then the effect of the redesign with these elements.

Now, what OSHA did is kind of interesting. Again, they were looking at a very large population. And they surveyed all of the industry and, again, by SIC code. They looked at the case studies. They looked at case reports and any actual scientific studies they could find.

On average, they found that there was a 51 percent increase. I think the range was from about 3 to 300 percent. So there's a pretty wide range of a productivity effect, but this is the average they came up with.

Again, what we want to do is take the data from -- and we actually have all of this data on hard copy from OSHA and build it into a database that will support the model. And, again, they came up with an average payback period of under ten months.

So, again, we can use this data to feed in. But the key is going to be how well we can link the SIC codes with the MOSes and the wage, grade, series.

Okay. Now, the cost of solution, there is a level of precision issue with this. If I'm looking at a set solution, again, I wanted to redesign a process, I can be pretty specific about the total cost of that solution because it's a thing that I can actually touch. But if I'm looking at a program effect, which is what OSHA did, we're going to have a little bit more of a problem.

So what they did is use some expert

experience, case reports, and studies. And they classified jobs. They grouped these jobs into categories, by SIC code into categories, and then they developed this range concept of interventions that had essentially no cost, interventions that had a maximum cost of probably 100,000. So it went from zero to 100,000.

The majority of -- it's a skewed distribution. And the majority fell into the no cost or minimal cost, under $100 range. Then they said that for industry by this job classification, most of these jobs based on this expert opinion and case studies fall into these ranges. And they followed this distribution, and then they extrapolated it throughout the civilian sector.

They have been criticized about this rationale, but honestly it seems very logical to me when I read the process, the thought process, that they went through and to come to this endpoint.

Again, if you have any other ideas of how to benchmark this, I'd greatly appreciate it. If you want to see any of the hard copies of these reports, I'd be glad to send those to you, too. Okay.

Now, the benefit calculation, of course,

with the health outcome, you are going to see some kind of residual risk. You can't eliminate 100 percent of that. And so what you will do is from that risk assessment code, you will again recalculate a risk assessment code with this new design and then come up with a lower weighting factor. And then that also is a user input point. So, again, you can calculate the effect of that change.

The OSHA, again, used a lot of case studies and interventions. And they did those benchmarkings. Now, the production outcome is a little bit softer because there's always a human element in there. You can go through the best activity-based costing model, but that doesn't mean that that's what's actually going to happen when you put that system into place. And building in that human element, that error element, into the calculation is a bit of a challenge to actually benchmark and quantify in the model. Okay.

So what our plan is is to continue the development of this. We're hoping to complete the conceptual model, the actual document, by December of 2000 and get a Web-based version up by April of 2001.

We have asked DOD environmental security for additional funding to help us validate this model with actual field data that we collect to, again, justify our assumptions or our expert opinions.

Okay. Next slide. So now what I'd like to do is summarize the questions that I really have back to the AFEB in regard to this cost-benefit model.

First of all, the biggest question is: Is this logic appropriate? Is this general reasoning appropriate? Does this thing make sense? And if it doesn't, what are the holes that you can see as we're going through the process? What level of detail would you recommend for the inputs, especially in terms of the job and the demographics? Because we can get general categories of jobs.

If you look at, for example, on the DMED, they do group and list it into very general categories throughout DOD. And we can use that model. There are enough similarities among those jobs to support this model with the detail, appropriate level of detail. Again, do we need to build in a gender, age, rank, and status factors?

The diagnostic categories versus the specific, and that's, again, linking the ICD-9 codes, nature of injury codes, and the VASRD codes. If you have any recommendations for that, I'd really be excited to hear those because, again, we need to be able to pool the data.

Department of Labor, the civilian categories are always nature of injury. The DOD health care system is using ICD-9. But, again, the diagnosis changes as they go through the process and then any recommendation about the service differences that we have noticed as we started looking at the data.

Any recommendations on the payment rates. That was specifically if you would recommend, again, looking at the DOD weights by region or as a general standard rate. How would you define an episode of care? And how would you track that through our existing databases?

Next. Any comment on the health/behavior issue and the decision-makers that I had brought up before in terms of who seeks care, at what point they seek care, and controlling for that provider effect if that's at all possible? Have we used appropriate work-relatedness

reasoning? Is there anything else we can do to tighten up that work-relatedness piece? OSHA benchmarking. Do you think that it's a good idea to go along with what OSHA has done, feed that into our model?

Our plan is to take that information and validate it with the ergo working group and other experts. If anybody wants to look at this data, you're more than welcome to help me validate it but just to say that yes, this can apply to DOD and our populations.

And then our last question is: As we go into Phase II of this modeling, we actually have to validate it. Which of the elements should we really focus in when we do that validation? Should we look more at the inputs to see if that really does link with the injuries and do record reviews? Should we look at the program outcomes or our health benefits outcomes? Which part of the model would be the highest focus? And in what way would you prioritize it?

I think that's my last slide. Okay. I'm sure there are some questions. So I appreciate your help and your attention. What questions do you have for me?

PRESIDING OFFICER LaFORCE: Yes?

DISCUSSION

DR. SOKAS: I have a question about when you categorize jobs in the military. For some of them if there is a requirement that you have to have physical demand criteria to see if someone can do this, some type is needed if you've got return-to-work criteria or it may just be that you want to see if someone ahead of time can go into a certain job. If you have that, that might be a little more precise than just the job titles. I just don't know for which jobs that might or might not be available.

LTC LOPEZ: They have classified jobs into heavy, very heavy, types of categories. Paul, you can help me out better with this one, but I don't believe they have any set criteria on return-to-work. That seems like it's more of a provider judgment that this person is fit and ready to go back into that MOS. That provider may or may not know all of the nuances of the MOS.

DR. SOKAS: So when they classify the jobs according to heavy or light or whatever, do they get specific about what that means in terms of bending and stooping and lifting and all of that

kind of stuff?

LTC LOPEZ: Yes. In very general categories, they do. They have MOS task lists. They can go down that. Sometimes they'll identify how frequently those are occurring, but the general ones in the big MOS book -- and I'm not sure if it's the same for the Air Force and the Navy or the Marines -- are that you have to be able to lift 100 pounds very frequently and under these environmental conditions.

Paul, if I'm missing something, chime in.

COL SMITH: You're right. They are not very specific. And it is provider-generated as to when they do return-to-work. I myself have seen huge variations.

The other thing that is sort of troublesome is classifying by MOS within the Army or AOC if you're an officer. Often you may have an MOS, like my AOC or MOS is 60-Delta, but I can work as a 60-Charlie or vice versa.

And my activities, in fact, may be much different. So you end up with a misclassification by us sitting there and a rather large one other than activities that are all military.

So there are a lot of problems involved in it that I think our civilian system is a lot easier to get. Our civilian workers are much easier to get a handle on because we have nature of injury cases, et cetera. At least we can draw from --

LTC LOPEZ: The big hole, again, with that, the civilian compensation system, is that that person actually has to file a compensation claim because under the GS or the wage, grade system, they can seek medical care under their benefits package and that, even though there is a definite work-relatedness factor in there, it never enters the information that we have. We only have compensation data.

Yes, sir?

COL DINIEGA: On the ergonomics cost-benefit model, the one that you want to put on a Web base, how many of those deals can be populated at this point?

LTC LOPEZ: Some of it has to be expert judgment. What we're looking at are the existing injury databases and Worker's Comp databases and feeding it in as well as the OSHA data that they did with all of industry by SIC code. Is that what

you're asking me?

COL DINIEGA: Yes. You know, there are a lot of deals that you have to get data for. I get the feeling from my previous experience that it's very difficult to get those data. That's number one.

Number two is I think ergonomics in the military is definitely not like ergonomics in the civilian sector. I think you have to -- what I would recommend as an individual in looking at this issue is that you're dealing with several populations. And data availability depends on what population you're dealing with.

So if you're going to deal with the civilian population, then you'll have a different set of data requirements and different difficulties in getting some of this data. If you're going to deal with active duty and look at their MOS, you know, job-related problems, musculoskeletal diseases, then you have a different population with different data requirements.

And then if you take a look at non-work-related stuff, then it's a totally different data set with its own set of problems. I just think at this point to try to get one

cost-benefit model that will look at it all, it's going to be too big and you should --

LTC LOPEZ: So what I think you're saying is that as one of the many imports that they start out with, they have to categorize it if it's military or civilian.

COL DINIEGA: I would say in order to validate the model, I would do a piece of the pie.

LTC LOPEZ: You need that endpoint validation.

DR. ALEXANDER: Yes, exactly.

COL DINIEGA: Right because it may be different requirements for every population. And then you want success so you can get funding, and I would go for the one that has the most data.

DR. ALEXANDER: I absolutely agree. I mean, I'm trying hard to focus on what you're saying. You put out 50 variables, and each one is so amorphous by itself and the quality control for each variable is questionable.

It would seem that a reasonable tact to take for step one would be to take one MOS, take the infantry men, or take something that represents a fairly large prevalence and work out the bugs with that one and if it works with one MOS, then

build on your model.

But to try to do the universe of the military with variables that have no boundaries to me seems like a gargantuan exercise in futility.

PRESIDING OFFICER LaFORCE: Joel?

DR. J. GAYDOS: Joel Gaydos.

Mary, in taking this approach, define some self-population within the total population as a more manageable type approach. How much data and information do you have right now with regard to uniformed people and civilians that would lead you to perhaps the group that would be best defined and the group that would be at risk and would be a worthwhile population and start working with it? It may lead to something in the future in terms of interventions.

LTC LOPEZ: Well, taking the same approach that you just recommended, I would probably look at the number of people to get the largest MOS group.

DR. J. GAYDOS: Right.

LTC LOPEZ: And I would not --

DR. J. GAYDOS: That may not be the one that's at greatest risk for contributing to most of the injuries.

DR. ALEXANDER: Or whether data are available.

DR. J. GAYDOS: Right, or whether data are available.

DR. MUSIC: Or where you've got a vested interest. My bias would be to start with the hospital corpsmen or somebody already in the medical --

DR. ALEXANDER: Nurses.

DR. MUSIC: -- arena who are going to be part of this data entry and data composition systems so that you get cooperation from the front end.

COL DINIEGA: Well, I think with the DMED, if you put in for the leading cause of hospitalization among active duty, I think the answer was knees. You know, that might be something to look at with MOS. And then if it focuses down through one large multi case coming from a single MOS, then take a look at that and then see if you can do the modeling.

LTC LOPEZ: Marc's folks have run these kind of queries before and come up with some great answers.

COL SMITH: Have you looked at all of

the safety data that was presented?

LTC LOPEZ: Yes. The safety center data is really weak. Yes, we have looked at that. It's about ten percent of the real picture. And it's a good indicator of what might be going on because it provides more detail about those actual incidents, but in terms of really rolling up and giving us solid populations, it's kind of --

COL SMITH: The reason I bring that up is because many times --

DR. J. GAYDOS: That would be a pretty high threshold.

COL SMITH: You miss a lot of cases.

CDR MURPHY: Oh, you do. It's got to be four days' work loss.

LTC LOPEZ: That doesn't mean we --

CDR MURPHY: So there's a big discrepancy right there.

LTC LOPEZ: Yes.

PRESIDING OFFICER LaFORCE: I wonder if I could try to summarize a little bit of the concepts. We followed your work now through a couple of Board meetings. And we're really quite impressed with, one, the energy and the leadership that you have provided in this very important area.

So I want to make sure that that is underscored and how appreciative we are of, again, your leadership in that arena.

Secondly, when we prepared the Board's comments last time, one of the areas that I want to emphasize is that the Board was interested in supporting further refinement of the cost-benefit model that you propose.

I think there is a bit of concern on the part of the Board. And certainly I would have to echo that concern that the approach appears to be, frankly, too comprehensive.

I would propose back to you if there was a way of being a bit more focused in terms of what Lynn suggested or as you reflect on this, that I would propose that you're considering finishing or developing the conceptual model by December of this year. And I would propose that that conceptual model come back to the AFEB.

LTC LOPEZ: I'd welcome that, yes.

PRESIDING OFFICER LaFORCE: And the suggestion that I would make or -- I don't want to say that I would make that sort of reflects the comments of the Board would be that that conceptual model be actually more focused or more narrow than

this presentation. And it may be focusing on either the nurse corpsmen or the recruit soldier.

It doesn't, frankly, make any difference to us. But what we would like to see is the model vetted in a way that's a bit smaller because I think the Board is concerned that in trying to be so comprehensive, frankly, it gets so daunting that the detailed work never allows you to sort of grapple with the model itself.

Would that be --

COL DINIEGA: And, in addition to that, the request for a status of the update of ergonomics programs to the services, I think that would be good for the Board to hear back on.

PRESIDING OFFICER LaFORCE: If we could?

LTC LOPEZ: Yes, sir.

PRESIDING OFFICER LaFORCE: And if it would be at all possible to have a draft before the next session or something that we might be able to sort of -- we're anxious to help you is what we're saying because, --

LTC LOPEZ: I appreciate that, sir.

PRESIDING OFFICER LaFORCE: -- as I said, I think you're doing or the Board feels that you're doing important stuff. And we want to see

it continue. Okay? Thank you.

DR. MUSIC: One further comment.

PRESIDING OFFICER LaFORCE: Yes?

DR. MUSIC: You talked in your slides about the payback period where the investment was recouped after ten months.

LTC LOPEZ: Right.

DR. MUSIC: I would point out to you -- and so much of this is marketing because you've got a lot of people to sell -- that that benefit is recurrent after that. Every ten months, it pays itself back off. And that needs to be made explicit. That's going to give you a lot more buy-in.

LTC LOPEZ: That's true.

PRESIDING OFFICER LaFORCE: Okay. Let's go on. Colonel Gardner, an update on mortality registry and a proposal for an injury prevention support center. Colonel Gardner, Chief, Preventive Medicine at Fort Bragg.

UPDATE ON MORTALITY REGISTRY AND A PROPOSAL FOR AN INJURY PREVENTION SUPPORT CENTER

COL GARDNER: I have to assure you I'm not here in uniform because I was on emergency leave and came directly here, rather than because

of a statement I made about the fiasco in adenovirus vaccine last month when I said that I was ashamed to be seen in a uniform.

(Laughter.)

COL GARDNER: What I want to do is go back to December '97, when we discussed mortality registry at the AFEB meeting and got the endorsement of AFEB on trying to form a mortality registry.

We put together a concept, which I'm going to go through quite quickly. I really have two talks here. I'm going to try to keep each one to ten minutes so that we can have time for questions.

Next slide. By going quickly, most of what I have to say, at the beginning at least, is what you have said before and is contained in this book on the second to last article, Page 57, from the military medicine supplement.

Why do we study military deaths? I think, next slide, it clearly is the most serious and a permanent health outcome. Routinely reported and investigated, it has enormous implications.

Mortality must really be thoroughly understood before you look at other issues. There

are those who say, "Well, they are already dead. So there's nothing to prevent." But if you really don't understand why these deaths are occurring, then you really don't know how to go back and prevent them from happening again.

Next slide. So we talk about mortality surveillance, first, second, and third level. In the civilian world, we have second level surveillance with 2,000 ICD-9 codes or more recently 4,000 ICD-10 codes in terms of cause of death.

In the military, we have five codes for cause of death. That is accident, illness, suicide, homicide, and hostile action. Even if we had the 4,000 ICD-10 codes available, that does very little to help you in preventing mortality because it tells you nothing about the cause of death of gunshot wounds to the chest. It tells you nothing about the circumstances.

The circumstances are where the prevention comes in. That's why you need the third level surveillance, to get the details, medical issues as well as the detailed circumstantial causes, so that you can implement programs that might prevent them from happening in the future.

Next. So because of that, we tried to establish the DOD medical mortality registry, where we would collect in real time all active duty deaths and collect all the critical medical information, the death certificate, the autopsy report, the AFIP consult, and their toxicology, which tells you about alcohol and drugs, and the eyewitness accounts from the investigative reports from the criminal and safety and other investigations, and then review both the medical and the circumstantial issues and maintain this in a computer database.

Next. Now, what I want people to understand very clearly is that DOD does have a casualty system, what they call the worldwide casualty system.

I've worked closely with them for the last couple of years. They have a very important role of providing notification to family and taking care of the remains and so on. But they have made it very clear to me that their job is to take care of the families who have given the ultimate sacrifice for their country and why the person died is of absolutely no relevance to their mission.

They not only don't have the expertise

to investigate the cause, but they don't want to know because they are afraid people will ask them why. And they don't have the expertise to give those answers.

So we really do not have except for what we have tried to do with the medical mortality registry and what the Air Force has recently put together in their Air Force mortality registry any system that tracks why service members die.

We have the safety center to look at accidental deaths and investigate, some of them quite thoroughly. That theoretically would cover up to half. But we really don't have much beyond that, at least in a comprehensive way.

Next slide. So what we're trying to do with the medical mortality registry is put together the review of the deaths, pull together all the information, and get the denominator data so we can calculate rates, and then give us an accurate, complete systematic data source for research and study of mortality-related issues.

Next slide. So so far what have we done? Well, we have pulled together all of the casualty data, casualty office data, which goes from 1980 forward. And that's what's published in

here. There's an abstract with a little more detail in your handout. And the first three slides I'll show you are from that next slide.

Then we've tried to from 1988 deaths forward collect more detailed information. We've been fairly successful with that, although it's a slow process without full resourcing.

Here you see the mortality rates by manner of death; that is, accident, illness, suicide, homicide, and hostile action. And then there are a few always that are undetermined. And you see the death rates have been going down. Particularly accidental death rates have been going down for the last 20 years.

Next. And you see that they're different in the different services. The Air Force is a little lower. I think that likely reflects the safety focus of aviation. And the Marine Corps is a little higher.

Next. And here you have just a listing of the hostile deaths, not very large numbers, but you see the big spikes that occur related to hostile actions.

Now, let's just talk about 1988 because that's what we know the most about at the moment.

Next. Here we have 892 deaths. Now, in fact, we're up over 900 since we got some more recent Air Force information.

The casualty office's numbers are either 815 or 830 depending on which report you look at. We get extra deaths because we're finding that those who are medically retired immediately before we die often don't get caught in the system and are not reported.

There are some other problems with the data, like we have reservists in here who are on active duty that are in the numerator but not the denominator and so on. Those are issues we're trying to deal with.

But you see that the number of deaths reflect the approximate percentages of people in the services. I haven't got yet to be able to get death rates on the '98 data, although we will get there next.

Here you have them split up by manner of death. And this is the best you can do with current data. Again, the current data excludes at least ten percent. But you see that 53 percent are accident, 22 percent illness, 19 percent self-inflicted, 3 percent homicide. That's kind of

the numbers we have been bouncing around. Eighty percent are injury, accident, suicide, homicide, or hostile action.

There are lots of biases here because if you get chronic disease, then you tend to get discharged and die as a civilian, rather than be kept as an active duty death and so on. So there are a lot of difficult issues here but ones that we can address if we're allowed to collect the adequate information.

Next. This is something that nobody has ever been able to do before, and that is look at the illness deaths and divide them up by cause. This is just some broad causes.

You see that there are very few infectious disease deaths. There may be one or two myocarditis deaths in the circulatory category. And the respiratory are not all acute asthma. Some of them might include pneumonia.

You see that two-thirds of all the deaths are circulatory and stroke. Again, that reflects I think primarily the fact that when you're sick, you get discharged, separated. And even if you die within a few hours, you may not get counted. And if you die within several weeks, then

you definitely don't get counted.

Next slide. Here are the accidental deaths. You see that 80 percent of them are transport, most of those POV, privately owned vehicle, accidents, about 50 or so government-owned vehicles in there, plus another 50 or so somewhere. Most of those, air, water, land are aircraft accidents, accidental deaths.

You can get this kind of data from the safety centers. They try to track all of the deaths. They do fairly extensive investigations of the government vehicle, the aircraft and government vehicle, deaths, although only limited investigations, for example, of privately owned vehicle deaths off base.

Next slide. When you look at the suicides, we have been able to split them up between firearm and non-firearm deaths, 60 percent. Seventy percent of homicides are by firearm.

Next slide. If you look at all of the firearm deaths, that makes up 15 percent of all military active duty deaths. Now, you have to remember that all military active duty are under 65. And so, therefore, all contribute to premature mortality.

In the CDC figures, when they present potential years of life lost, they're excluding 73 percent of the deaths which occur at age 65 and over, but we don't do that in the military because they're all under 65. So all of these are potentially preventible or at least contribute to years of life lost figures.

If you exclude the illness deaths and the transport acts of death, actually, we're at firearm is 41 percent. We have looked in a little more detail at these. And with very rare exceptions, these are all privately owned weapons and not government weapons that cause these deaths.

Next slide. We were looking at exercise-related deaths as being a long-term interest. And trying to do that here, we have found it very difficult. There's no ICD code for exercise, nor are they often identified.

In the Army, we have been able for the last four or five years to get them to identify what they thought were exercise-related deaths. Then we have gone back and pulled them and looked at all of those.

So we know we have an under-count here of those related exercises. But we at least found

34 deaths related to exercise. The most interesting part of this is most of these are related to running.

Next. You see that half training there usually means PT. Physical exercise generally means running, maybe running on a treadmill. And then the PFT is the physical fitness test. That always is during the running event. So three-quarters of the exercise-related deaths are during running, with a few marching and sports.

Next. Here I was quite surprised to realize that -- you know, I always thought of coronary artery disease deaths as occurring over age 40, but we have lots and lots of them in their 30s and even a few in their 20s with coronary artery disease deaths.

But if you cut off at either 30 or 35, you get a picture like this. Nearly all of those over 35 are ischemic heart disease. And nearly all of those under 35 are not ischemic heart disease, but, rather, relate to other forms of heart disease, such as anomalous coronary arteries or hypotrophic cardiomyopathy. And a significant number are related to heat illness and heat stroke also.

That's I believe the end of what I have on the mortality update. Next. Just a little follow-up with Sir Roger Bannister. If you remember, he's a British neurologist who when he was a medical student in 1953, I believe, became the first person, first human being, to ever break the four-minute mile. And I think he gives us some sage advice here.

Let's move on to the next set of slides about the Armed Forces Injury Prevention Support Center. Here is a concept that's related. As I talk to you, as I mentioned, next, the 80 percent of military deaths are injury. And at least half of hospitalizations and other medical encounters relate to injury, disability.

And so, if you remember, about a year ago, we gave you copies of this big thing you had to carry home, which was the atlas of injuries in the military that came out of the Injury Prevention and Surveillance Working Group.

We have taken here a very broad definition of injury, which includes nearly 90 percent of deaths. That is accident, suicide, homicide, noncombat violence, disability, and occupational hazards.

Next. I think that we have tried to as a recommendation from this committee and also as a recommendation from the AFEB report, which came out in February or March-April, in American Journal of Preventive Medicine, and also from the Injury and Occupational Illness Prevention Committee, that we needed to institutionalize injury prevention and injury data collection.

And so the committees have put together a concept, the proposal. That is we're trying to float up towards higher channels. And we wanted to get your comment on this as well as your reaction to how we're doing on the mortality issue.

By the way, on the mortality registry, we started that at the Armed Forces Institute of Pathology. We never have gotten complete funding. We got about a quarter of what we needed to kind of limp along and get things going. And as we were about to emerge I think with something that really was workable, they decided that since we didn't have a billet for it, I was transferred to Fort Bragg. So I left there July 31st and am now down at Fort Bragg. I am Chief of Preventive Medicine down there.

So what's going on now is what I'm

trying to do long distance and on weekends. And we're trying to develop a more stable funding base and a billet, at least one billet, to perpetuate, expand, the mortality registry operations. And we have developed, incorporated it into part of this Injury Prevention Center, Support Center, a concept, too.

The concept of the center is to compile and assimilate available data and basically to be able to provide updates to this outlet in more accurate, more meaningful, and more useful ways than we did with the seven-year process that produced this document and to monitor and facilitate military injury research, to promote and improve data quality completeness and to make policy and program recommendations regarding best practices. So let me go through those missions one at a time.

Next slide. The current problems are that we have a number of injury and safety working groups. These are staffed by people with full-time jobs that have this as an extra duty and minimal resourcing for conducting their real business.

And we have a lot of investigations that go on in various different areas and a lot of data

collection or data creation in the various different areas of mortality investigations, disability, hospital databases, and so on.

Let me put it this way. There is not a very good, solid working relationship between the medical community and the safety community that provides for the kind of combined effort that we really need to address this issue. And it's not either of their fault. It's just that it hasn't come together the way it needs to do to really empower injury prevention.

We have databases in lots of different places, as illustrated in this book, lots of different places. There's very little standardization between the data sources, between the services.

So you can't really compare data you got from one source with data you got from another source, even within the same service, especially between services.

And so all of these kinds of issues need to be addressed. And they really need to be addressed by a full-time staff that focuses on these issues and helps implement the kind of policies and procedures to give us a good handle on

exactly where we are and where we need to go.

Next slide. I think we're really suffering from a lack of public confidence. The Gulf War illness issue really created to a large extent but exacerbated this problem dramatically because we weren't there at the time the questions were asked about a mystery illness with the data to say, "Look, here are the death rates before, during, and after. Here are the disability rates before, during, and after. Here are the hospitalizations rates before, during, and after. And they haven't changed."

Instead, we say, "Well, we don't know." And the public just can't believe that we're so incompetent as to not know what is going on with our people that they assume that it's a coverup.

Because of that, we've lost tens, if not hundreds, of millions of dollars in resources that have been diverted and in loss in public confidence in this issue.

I think understanding mortality is one of the first steps that has to be taken. And a lot of things have been done in terms of medical surveillance to try to address these issues. But we've only taken the first step, and we're really

not to where we need to be.

Next slide. So first we talk about compiling available data, and that's basically the process we went through to develop this atlas. The atlas does not give us the answers. The atlas gave us an insight into the data sources. And we were able to pull from those data sources certain kinds of data, but we weren't really able to scientifically evaluate those because of the problems I've mentioned.

We have mortality data. We have hospitalization, ambulatory visits, health habit data. We have disability data. We have personnel systems, lots of different places, where we can given adequate resources put together a very good picture of what is going on.

We can do a much better job in the military because of the availability of these kinds of data sources than can be done in the civilian community. Yet, because we haven't put the resources into or the attention, drawn the attention toward that, we actually are not doing nearly as well as the civilian community, even though we have the potential to do much better.

Next. So we take the data, review it,

synthesize it, put it together into a true picture of what's really going on. We need to support the missing elements; that is, mortality and the comparability of the data quality, and track the progress of recommendations and provide the data for specific policy and research issues.

Next. Next slide. The second area is to monitor and facilitate research. That is, we have actually a fair amount of injury research going on in the military, but it's done kind of -- well, there is not a coordinated effort, where all of the people do an injury search, even though what other people in the military are doing. I think that's part of the process of the goal of this center, to help provide the communication links to bring injury researchers together.

In May, at the Uniformed Services University, we sponsored a conference on injuries in the military, a threat to readiness. And I think that was a good beginning of some of the kinds of things that need to be done to both raise the awareness and allow the researchers the opportunity to find out what the people are doing and work synergistically.

The third area is to promote data

improvement and the quality of completeness of data, actually do some investigations on these. Some preliminary work has been done by Dr. Amaroso, for example, looking at safety center sources for injuries and medical sources for injuries and finding that they may overlap only 15 or 20 percent of the time and work out ways to resolve some of these discrepancies, work on standardization for coding and collection and provide staff support for the injury and safety committees and working groups, which really, as I said, are staffed by people who already have full-time jobs and don't have time to do the work that it takes to get something accomplished.

Next slide. Finally -- and this is actually a very big area -- is to make policy recommendation. And this involves review both of the literature and of existing programs in injury prevention and evaluate their effectiveness so that we can make statements about the better prevention practices and provide -- in the same way you provide clinical guidelines and clinical algorithms for clinical treatment, you can do the same for prevention efforts and prevention programs. That involves pulling together this expertise of injury

researchers and people involved in these areas so that you can have expert committees that can address the issues, very specific issues, and decided on what our best practices at the present are and help get those implemented as policy throughout DOD. This may involve some consensus conferences like they have at NIH and so on.

Next slide. Well, the rest of this is just kind of how to put it together, and that's all up in the air. And I'm not sure it matters very much how it is put together as it does that something happens.

There needs to be academic affiliation. There needs to be a partnership with all of the people involved in injuries. There needs to be a virtual collaborative group of all DOD injury researchers and safety and health promotion professionals. And it needs to provide support for the current injury committees, the Prevention, Safety, and Health Promotion Council and Defense Environmental Security Council, who have both the health and safety aspects.

Next. Perhaps one way to do this is in that diagram, which you can see on your paper. And it has to involve a network if the next slide will

come up of partnerships with all the different groups, where we can have the kind of collaboration that we need.

What are the advantages? Well, the advantages are that it will institutionalize data support activities within DOD that relate to all of the issues, population, health, force health protection, deployment health issues, quality assurance, and so on. And it will ensure that our DOD injury surveillance and research efforts data will be collected and used in policy and decision-making.

Next slide after that one if you can get there. And it will implement the recommendations that have been made by the various committees, including this Board.

Next and next and next. There we are. I'll leave the rest up to you. We're talking about a two or three million-dollar a year budget for a central organization that would put together these issues.

I think we've got a lot of support for this from the safety community, environmental security, and from the health side. We presented this this summer to the Environmental Security

Council and the Population, Safety, and Health Promotion Council. Both responded very favorably, and we'll see how long it takes to get something going in that direction.

Perhaps what AFEB might be able to do if you think it's a good concept is say so in writing and send it to the right places so that we can move forward.

Any questions?

PRESIDING OFFICER LaFORCE: Questions for Colonel Gardner? Yes, Julian?

DISCUSSION

DR. HAYWOOD: Do you see an area of collaboration with the ergonomics program that we just heard about?

COL GARDNER: Absolutely. There needs to be a coordinated effort in all respects. The ergonomic issues are relating to the better prevention practices and so on, and I think that's a big part of what we have tried to design.

DR. HAYWOOD: I, for one, would like to strongly endorse the use of the AFIP mortality and the military mortality databases in collaboration because I think that's a very strong national resource that ought to be exploited.

I'm disappointed that half the years that I've been on this Board to hear you say that you haven't advanced beyond what I heard I think in my first or second meeting, with which I was strongly impressed.

COL GARDNER: Well, we've got a good start, and we've learned a lot. One thing we've learned is that nearly every military death is investigated. They're all supposed to be investigated. The level of investigation varies, but there is an investigative report on almost every single one that tells you the circumstances and so on.

The problem is those remain at the local level. The concept I developed for a mortality registry was not to go out and do further investigation but, rather, simply to pull together all of the information that is being collected into one place as a repository so that we could pull together all of that information into one place and look at the big picture, as opposed to one death at a time.

PRESIDING OFFICER LaFORCE: I would say the synthesis -- I agree with Julian. This synthesis in terms of U.S. military deaths is,

frankly, from our standpoint pretty reassuring, particularly in terms of the trend data with accidental deaths.

And also something that I don't think has been sort of celebrated enough, when you look at U.S. military deaths 1998, only four from infection and think of the thousands of deaths that occurred 30-40 years ago, you know, --

COL GARDNER: Well, the military death rates --

PRESIDING OFFICER LaFORCE: -- that's astonishing.

COL GARDNER: -- in general are very low compared to the civilian rates, half in many circumstances and half to three-quarters most of the time.

And nearly all military deaths get autopsied. We probably have well over a 90 percent autopsy rate. Now, they don't all come through the medical examiner's office. Only about a third come through the medical examiner's office. But the potential there is to get about 90 percent.

DR. HAYWOOD: That's extremely important because it's the only place where the level of autopsy and complete mortality data is being

maintained. Everywhere else it has gone down dramatically.

PRESIDING OFFICER LaFORCE: The other thing is I agree with you in a really fundamental way. The mortality is an absolute phenomenon and something, a level of responsibility that is enormous and one that deserves as much attention as you're providing it.

Yes?

DR. ALEXANDER: I'm intrigued. I agree with you that this is important. I'm confused with the process. I'm starting to feel like I'm part of a review committee that's supposed to stamp or not stamp under-funded epidemiological projects of interest to the military. I don't know.

Is that our role that under-funded programs come here and pitch to us and we nod and then we make a recommendation? I'm confused.

PRESIDING OFFICER LaFORCE: Occasionally we say no.

DR. ALEXANDER: That's good.

PRESIDING OFFICER LaFORCE: Occasionally we say no.

DR. ALEXANDER: How is that process determined? I mean, it's like: Are all

under-funded epidemiological opportunities given a fair chance to present to us? I'm confused about what our role is.

COL DINIEGA: Let me just set the record straight here. If there is no formal question to the Board, you don't have to say anything. If there is a formal question to the Board, then we have to respond.

DR. ALEXANDER: Then we have to.

COL DINIEGA: If the Board feels -- and on several occasions, they have. On getting informational briefs, they felt strong enough to make a statement, either support positive or negative. They have done that. But there is no obligation as far as I'm concerned for the Board to respond to non-formal questions or information.

DR. ALEXANDER: If we feel really strongly about something, is there a way to follow up on our recommendation where we can facilitate the action that we desire or is it this -- I'm trying to understand what we do. Does this stop here?

COL DINIEGA: On a recommendation?

DR. ALEXANDER: Yes.

COL DINIEGA: No. You can ask for

feedback on what the services have done. But, remember, now, the Board, as with anybody else, even division surgeons, operational surgeon, et cetera, makes recommendations.

It's an advisory capacity. And the people you're giving the advice to may heed or not.

DR. ALEXANDER: It's very compelling. These are things that make tremendous sense operationally, programmatically, big picture health U.S. as well as military health. I just don't know what we can do to --

PRESIDING OFFICER LaFORCE: What we can do is precisely what the Board has been charged to do. I don't think it's an indictment. I mean, it's just basically within the charter of the Board to serve as a senior advisory board to the military on epidemiologic matters and to offer specific guidance when requested in terms of specific items.

The Board actually has identified items over time and has paid attention to certain issues. I mean, the mortality issue came up two or three years ago. The Board has been very interested in the evolution of this particular piece of work and congratulates Colonel Gardner in terms of what has happened to this piece of work.

Similarly, the ergonomics work, which began with just a discussion at a subcommittee several years ago, that's now moved a fair amount as a result of subcommittee activities. So sometimes it takes a little bit of time, but it all seems to work.

Yes, David?

DR. ATKINS: David Atkins.

One thing that wasn't completely clear is the extent to which you have similarly complete information on major disability because one thing that occurs to me is while we all agree mortality is the major endpoint, you actually might have a greater potential to have an impact on things that cause major disability, both in terms of preventing them. That is where the bigger burden of disease --

COL GARDNER: Absolutely. And the causes of disability are different from the causes of death --

DR. ATKINS: Right.

COL GARDNER: -- to a very big extent. And that's kind of my next vision, but I can't get this one gone yet. So I have looked first at this. First we're looking at military active duty

deaths.

The next step would be to look at the deaths that occur after you leave the service and see how many of them are related to what you did in the service.

And another next step is look at disabilities. And there are disability agencies who do a little bit of that. Paul Amaroso can tell you more about what they do. They're busy working out benefits. I mean, their job is to give the benefits and to work out the issues, the medical issues, related to giving the benefits for disability.

You know, the Army alone spends one and a half billion dollars a year disability payments for people who are disabled while on active duty. And you triple that, almost triple that, when you look at all of DOD itself.

Then the VA, of course, has another 15 or so billion dollars that they spend on disability-type issues from service members. So it's a huge area with a large potential for economic savings as well as reduction in morbidity.

DR. ATKINS: I guess my simple question is: Is there a standard accident investigation for

serious accidents, even if they aren't fatal?

COL GARDNER: Yes. Safety centers do that.

DR. ATKINS: So that's how they handle the safety?

COL GARDNER: Safety centers do that. And in the Army, the criteria begins at one day of work lost. That is, not today go to the clinic, but if you're off the next day, that counts as a safety center accident. The Navy you said was four days, something like that?

CAPT SCHOR: Navy is four days. The Marine Corps is that day.

COL GARDNER: Yes. But if you're running and you collapse and it's deemed heelless, then that's an environmental exposure and, therefore, an accident and they investigate it. If it's a heart attack, that's illness and it's not investigated.

PRESIDING OFFICER LaFORCE: Yes?

LTC MacINTOSH: This is Vic MacIntosh.

You mentioned the Air Force mortality registry. Could you comment or give just a snapshot of how you feel about that?

COL GARDNER: Well, the Air Force was

there when we discussed this in December of '97. They picked it up faster than I could get going. And so they started collecting. They did a wider spread in terms of their population. They're looking at federal civilians and others and retirees.

Initially they were just collecting death certificates, but I convinced them to start collecting autopsy reports. And they're starting to do that, too, now. They're updating.

They're moving them faster, fairly quickly, in that respect. I just saw their report. They now have about 1,600 active duty deaths and about 16,000 total deaths in their database. Most of those, of course, are retirees.

LTC MacINTOSH: Thank you.

PRESIDING OFFICER LaFORCE: Okay. Let's close with Major Pavlin's presentation on West Nile surveillance.

DOD WEST NILE SURVEILLANCE PROGRAM

MAJ PAVLIN: This should be short and sweet. You remember who I am. One thing that DOD GEIS have been working on is assisting DOD Health Affairs in accumulating West Nile surveillance data.

Next slide. This is a little recap. You probably all know -- this is in your notes that are being handed out to you -- that there was an outbreak the first time West Nile virus had been seen last year in New York, New York area, ever had been seen in the United States.

So because of that, next slide, the CDC had developed -- and it's kind of funny I'm standing up here talking. Dr. Ostroff is in the audience. He's the West Nile czar. So he could probably recite all of this and has the latest numbers off the top of his head of ever bird that died of West Nile this year.

These are the five points that the CDC wanted to do this year in terms of surveillance. And they approached DOD to say: Hey, we'd like to know what you guys are doing. We can share some information.

Next slide. This is the area that originally had been planned, that the CDC had planned on looking at for West Nile virus surveillance, which it could closely monitor and offer some funds to those states to assist them in doing their surveillance programs.

Probably in retrospect, that upper New

England area of New Hampshire, Vermont, and Maine probably should have been included, but it's always easy to say that after the fact. So these are the areas that have been planning their West Nile virus surveillance plans.

Next slide. You can kind of just go through the next two or three slides here. They're all in your notes. As we looked at in this area how many bases that we had, next slide, next slide, we realized that there is a whole bunch of them. These don't even include -- there are all of these naval air stations everywhere, and it doesn't include all of the National Guard, and it doesn't include just reserve installations. So you can see that there's a lot of areas that needed to be covered.

Next slide. This is the data that the CDC is requesting and is getting from all of the states as well as from DOD. So it's not just when you have a positive mosquito or a bird but actually trying to get some kind of background rates.

If you have one mosquito pull that is positive, that is out of how many mosquito pulls have you taken? So you can get an idea of maybe a little bit of the prevalence or the incidence

that's going on out in that area so you can see that, again, actually how many trap nights, how many mosquitos were you able to trap? And then how many of those did you test? What kind of species are you looking at and so on? And the same for humans. How many samples are you testing, let alone how many are positive?

Next slide. So in DOD, Health Affairs put out a memo about three months ago now trying to consolidate some of this DOD information and named GEIS as kind of the coordinator of all of this surveillance data.

Still we wanted to maintain that everyone still should report, all of the public health services still report, their positives or any of their information, as they usually do, through the local health departments.

And I'm sure they're still doing that and also to the CDC as needed, but they would also be reporting this information to us so we could collect it. We weren't telling anyone they had to do surveillance, but if they were doing it, we just wanted to know what they were doing.

Next slide. These are some of the DOD efforts. Right now probably the main hub of the

West Nile virus surveillance activity going on right now is at CHPPM North. That's the Center for Health Promotion and Preventive Medicine North. It's not up at Aberdeen. It's up at Fort Meade, Maryland.

The entomology section there has been very active in going out to Army but other installations as well and teaching them how to do the mosquito surveillance and assisting them in doing testing.

As far as DOD is concerned, I know they can do it at AFIP, but I believe CHPPM North is the only one doing mosquito testing for West Nile virus in the DOD. So any mosquitos that get tested in DOD are getting done up at Fort Meade, Maryland.

USAMRIID obviously is available for any kind of human testing, virus isolation, could take some animals if needed to, but I believe most of those are going through the USGS facility in Wisconsin.

The North Atlantic Regional Medical Command for the Army is also very active, put out a lot of information to the installations, and is collecting and kind of consolidating the data as well.

And the Army Veterinary Command is assisting with getting all of the animals tested, most of them, again, going to their facility in Wisconsin.

Next slide. For the Navy, the Navy actually received some funds from the CDC to kind of determine what their capabilities were and what surveillance was going on in the Navy.

And those DVECCs stand for, if I can remember, Disease Vector Ecology and Control Centers in Jacksonville and in Bangor as well as in the Naval Environmental Preventive Medicine Unit Number 2 in Norfolk.

They conducted surveys to determine what could be done, what was being done. And they have found some installations, those four that are listed, that are working with local health departments in helping them maintain some of their sentinel chicken flocks as well as they were having them do some of the mosquito testing for them. The Navy isn't doing any of their own testing as far as I know. They do have procedures in place for collecting and processing any kind of dead birds.

Next slide. The Air Force has been having a very active mosquito surveillance program

that they have had for many, many years, but it's not a testing. It's simply surveillance for speciation. And so they send this to us every week. We get this data every week.

Dr. Chad McHugh down at Brooks Air Force Base has a lot of mosquitos mailed to him, interesting job. He goes through and speciates them. Some of the Air Force bases have decided to get some of their mosquitos tested, and those have been done for CHPPM North as well. And those are some of the ones listed. They've sent us samples.

Next slide. Just a little bit of data for all of you who don't read your ProMeds right on time. This is some of the latest. The maps are a few weeks outdated, but I think as of probably about a week ago, the numbers are pretty on target. These are some of the areas they show here in the U.S. that have had positive mosquito pools.

Next slide. And this is some of the more recent numbers. You can see a lot of different species of mosquitos have been reported, a new one in *Anopheles* on genus. So that's interesting in the New York City area.

Next slide. And for birds, you can see again Vermont, New Hampshire, and Maine had not

been originally part of the surveillance plan. So they have not been reporting data. But you can see that it goes right along on the Vermont border.

Next slide. Steve, did you think it was going to go so much north, as opposed to south? It's I think a big surprise to everybody. This is some of the birds that have been seen, including some weird things like cockatiels. But so far the sentinel chickens haven't burdened that much. I think there were some other ones, but I couldn't find a record of exactly where they were. Definitely one in New York State had become positive.

Next slide. And humans, most of you have heard about this.

Next slide. So far nine have been tested positive. That's one man in New Jersey, who is the youngest at 43 years old, and then in New York City 8 more people. It started out on the older age range, 70s and 80s. Then the more recent ones have been in their 50s and 60s but no deaths so far.

Next slide. Some interesting new species coming through recently: the raccoon in New York City. There are also some bats in Albany

and one other area in New York State as well as the horses, like we saw last year.

Next slide. So far in DOD, we have seen very little. I don't know if that's because we've done great eradication efforts or what, but so far we have had one mosquito pool tested. CHPPM has tested probably as of today over 2,000 mosquito pools. So they're keeping pretty busy, and we started this in the beginning of June. It was from a pool of *Culex pipiens* found in Fort Hamilton, New York. That, again, is in New York City. So that's not surprising.

But they immediately went up there and found the breeding site where they feel that they mosquitos came from. And they were very quick to point out it was from off post and it was right outside the gate. They felt that this was probably where they came from.

They did also note that this pool was taken right before they did spraying. And New York City had found some positive birds near that area. They had done spraying on the day after they had collected these mosquitos, and they haven't seen a problem since. So hopefully that will keep them down.

Next slide. Birds and humans. These numbers are probably not that up-to-date because they take about a month lag to get to us from VETCOM. But we have tested. DOD has sent a number of birds for testing. So far three have come back positive from West Point.

We collected at the end of August a house sparrow and two cedar waxwings. The CHPPM North went up there. They got those test results and made sure that they knew how to do their good mosquito surveillance, told them how to get rid of all of their mosquitos, and tried to decrease the risk of that. So far the numbers I have been able to receive, five people have been tested, USAMRIID-DOD people, and no positives to date.

Next slide. So, in conclusion, I think CHPPM North and the other, the Navy equivalents and the Air Force equivalents, are doing a very good job getting out to the installations and setting in some preventive measures.

Colonel Cannon from CHPPM North wanted me to emphasize that probably the best thing we can do is what they did do and we need to do every year, start very early in the season and do some really good surveillance.

He had maps of the Fort Meade installation of every single sewage drain that went through the entire installation so that they could find the breeding grounds. They could destroy them if they could or apply larvicide if needed.

So, with that, they have a draft program in place should any positives come up on how to go in, positives for mosquitos or for birds, to go in and try and eradicate any source of spread to people. And that's as far as I know on West Nile.

Are there any questions?

PRESIDING OFFICER LaFORCE: Comments probably from Steve, who knows?

DISCUSSION

DR. OSTROFF: I spend all of my time dealing with West Nile. Well, I think that's a pretty comprehensive summary. I mean, the DOD has been very helpful to us, not only in the things that you have mentioned, but they have also had personnel go out to assist with training, particularly in areas that don't have a long experience in doing some of the mosquito-trapping activities and taking part in the teams that have been doing some of the more intensive surveys.

And then USAMRIID has been wonderful.

You know, there is research that goes on at USAMRIID looking at competency of mosquito vectors for various pathogens. And there had been a lot of work done by Mike Terrell which I think has gotten a lot of attention recently because one of the interesting findings this year is the introduced virus and the introduced mosquito being *Aedes japonicus*, which is a mosquito that only came to the United States two years ago. And Mike had been working on that mosquito. So that was very helpful.

Also, USAMRIID screens antiviral compounds to look for potential efficacy. It's actually been an issue for us because there is some experimental work that was done out in California looking at the potential role of ribovirin, at least *in vitro*, in cell culture. And now that's sort of been translated into -- at least in one of the patients this year, ribovirin has actually been used.

Just a couple of points. Number one, sentinel chickens have been a total flop. We don't understand why, but they're all over the place. And we have the one lone positive sentinel chicken out of this tremendous effort to use sentinel

chickens. And it was actually decided based on extremely good data.

We did a lot of experiments over the winter where we experimentally infected chickens. And they looked like they should be the perfect sentinels because when you experimentally inspect them by infected mosquitos feeding on the chickens, they develop a beautiful very low-titer viremia and developed a brisk, beautiful antibody response. We have literally had dead birds drop right next to the sentinel chicken cages and the sentinel chickens don't turn positive.

The interesting thing is that --

PRESIDING OFFICER LaFORCE: Good for the chicken.

DR. OSTROFF: Yes. They're fat and happy in the cages. But watch the sort of geographic range sort of tremendously expand this year. In New York State, it's basically as far west as you can get in New York State, in Niagara Falls and in Buffalo. It clearly has to be across the border in Canada, although the poor Canadians decided to put sentinel chickens upside down --

(Laughter.)

DR. OSTROFF: -- beside their border,

which obviously isn't going to find the virus.

At this point, there are a couple of issues. When it gets into western New York -- I mean, one of the things to keep in mind is that the birds are now migrating for the winter. And the birds that are in western New York State do not migrate down the eastern flyway. They migrate, a lot of them migrate, into the Midwest. And so we're particularly concerned about places like Ohio and West Virginia that the virus we will see spread into those areas.

The likely explanation as to why we didn't see it go south last year is that in some work that has been done in the U.S. Geological Survey in Madison, it's now quite apparent that this virus is uniformly lethal to crows, that if you experimentally infect crows, within 7 days, 100 percent of them are dead from this virus. And the same is true with many of the other migratory birds.

So probably what was happening is as they were leaving New York last fall, seven days sort of got them as far as Baltimore. And then they were all dead. By that point, there weren't enough mosquitos in October to sort of pick the

virus back up and move it to other birds that were going further to the south.

This year we see the virus further to the south much, much earlier than we saw it last year. And so there are still lots of mosquitos around. Already the horse in New Jersey -- there are now two horses in New Jersey. One of them was outside of Atlantic City, but the other one is in Cape May, Cape May being the major stop on the eastern flyway.

And so we think that it will be very soon you'll see in Delaware and along the sort of the Eastern Shore in Maryland and Virginia that it's sort of been -- we're very concerned about Assateague and Chincoteague and places like that, where these horses are. And the National Park Service has been working with us on some of these issues.

I recently heard that there was a dead crow found on the Mall downtown. So that's being looked at as well.

MAJ PAVLIN: We found one in the parking lot, but it was negative.

DR. OSTROFF: But it was negative, yes. We're very interested in the places where we

haven't found virus yet, Pennsylvania, Delaware, Maryland, because it will probably pretty soon be here.

The other thing just worth mentioning is, despite the fact that the virus is some much more widely circulating this year than anything that we saw last year, it's really gratifying to see only nine human cases because the risk is certainly present.

We don't understand why it sort of shifted in New York City from Queens, which is where it was last year, the big hot spot. This year it's Staten Island. And we think that part of the reason for that is that when we looked at live birds last year in the area of Queens that was most affected, more than 60 percent of them had been infected. It doesn't kill all bird species. There are some bird species that it basically doesn't affect at all.

And so what we think it actually did was create a herd immunity among the bird populations in that part of Queens. And so basically it looked for areas that weren't infected last year, and that's where it found Staten Island.

So far the vast majority of the human

findings have been in Staten Island, but we know there's a lot of virus around. And so not seeing a lot of human cases, despite much better surveillance, is pretty gratifying.

We don't know what role the weather has played. It's been really very rainy and cool up there. We think inadvertently people aren't engaged in as many outdoor activities. And when they are going outside, they tend to wear windbreakers and long sleeves and long pants because it's been so cool. So that may actually have been self-preventing exposure to the virus, but we'll take it.

We've still got a few weeks to go. So we're not out of the woods yet.

PRESIDING OFFICER LaFORCE: What about next year?

DR. OSTROFF: Next year will be a real problem for several reasons. Without a lot of human disease, the jurisdictions up there are going to pull their resources out and sort of shift it over things and not do quite as much as it is here. So we're concerned about their ability to sustain their effort next year.

Also, I mean, you can think of this as

sort of like taking a pebble and throwing it into a pond. What we're seeing is this virus very gradually sort of ripple out. And so we think that that is what is going to continue to happen in the next couple of years.

I think the other interesting point is what it is doing to wildlife up in the Northeast is that it's highly lethal to many of the bird species. Even some of them that haven't been so affected yet, like bald eagles and sort of these other raptor species, are apparently also highly susceptible to this virus. So it will probably change.

COL GARDNER: Sparrows, blackbirds.

DR. OSTROFF: Well, house sparrows don't seem to really get sick with this. You see, the number two after crows has actually been blue jays. But most of that, like in Maryland, for instance, they collect crows. They won't look at anything other than crows.

COL GARDNER: In most of our viruses, there's a lot of apparent infection and serosurveys show a big ratio.

DR. OSTROFF: Right.

COL GARDNER: That's been true also?

DR. OSTROFF: Well, we did a serosurvey last year in Queens. And in that serosurvey, I think the 2.6 percent showed what appeared to be asymptomatic or less symptomatic infection. When we actually looked at those people that were seropositive, 30 percent of them reported a recent febrile illness compared to 10 percent of the seronegatives. So we think, actually, some proportion of them have less severe disease.

We are very interested. And what we'll be doing in October is actually trying to repeat some of those serosurveys. But, instead of doing it in an area that had a lot of known disease, like Staten Island, we're interested in doing it in areas that had very intensive transmission in mosquitos and birds but haven't reported human illness because the question is: Are they potentially missing some human illness or is the transmission dynamic very different in a suburban area, where there aren't as many people around and there are a lot more birds?

And so the mosquitos are quite happy to bite on the birds since they don't bother with those few people that are around. So we're trying to answer that question so that we would know

practically what to advise next year if they need to spray.

DR. HOKE: Are you aware of any work with the ability of other flavivirus vaccines to stimulate antibody and neutralize this West Nile?

DR. OSTROFF: Well, there's some. I mean, the question of the vaccines is an interesting issue. Actually, looking at birds specifically, you know, there is a concurrent outbreak right now in Israel.

The Israelis actually vaccinate their poultry, their captive beast flocks, for instance. And they vaccinate with something called Turkish Meningo-Encephalitis Virus, which is apparently a problem in the Middle East.

It's a flavivirus. And they claim that it has cross-protection against West Nile, but this year we see they're east dying from West Nile. Our impression is that that always hasn't worked.

There is work that Tom Monath, who is now up in Boston, has actually gotten some funding from NIH to look at the development of a West Nile vaccine.

His approach is to take the yellow fever vaccine, introduce West Nile genetic sequences that

would then produce surface proteins that are directed against what West Nile is to create sort of a chimeric vaccine. He claims he can do this in about 18 to 24 months. But that's sort of the lading candidate for a potential vaccine.

DR. HOKE: I think you should always try to formulate and activate a whole virus vaccine first. We worked on one here about ten years ago, but it was deemed not militarily relevant for good reason. And we stopped working on it, but the seeds are still in the freezer.

PRESIDING OFFICER LaFORCE: Are they?

DR. HOKE: Yes, indeed. Ken Echols did that work with a collection of viruses to see which would grow the best in the cells. And that's what we have.

DR. OSTROFF: This is apparently quite an unusual strain of West Nile. It's one that only showed up in '97 and hadn't been seen before that.

DR. HOKE: But no one specifically looked at Japanese encephalitis vaccine antibody as a neutralizing agent?

DR. OSTROFF: No.

PRESIDING OFFICER LaFORCE: Yes?

DR. J. GAYDOS: Dr. Ostroff, is there

any indication that multiple infections might be involved in the more severe disease? Do we know that all people who died died from their primary infection?

DR. OSTROFF: Well, if you look at the fatalities from last year, there were seven. The average age of those individuals is 77 years of age. So they were way on one end of the spectrum.

The comment that Julie made is very interesting, that the amount of disease manifestation seemed to differ by age and that if you look at the under 65, the vast majority of them have meningitis and if you look at the over 65s, they tend to have the more severe encephalitis. And we think that that probably has more to do with who dies and why they die.

This year there is only one really severe case. And that's this very unfortunate 87-year-old woman, who remains in the intensive care unit in New York. She had the terrible misfortune of tripping over an electrical cord in early August and fractured her hip and got admitted to a hospital for hip replacement surgery and then seven days postoperatively, actually, while convalescing developed febrile neurologic illness.

The clinicians taking care of her actually had the thought to think of West Nile. You know, an 87-year-old woman convalescing in the hospital from major surgery, they actually thought of the diagnosis. And that's what she had.

DR. BERG: Nosocomial infection?

(Laughter.)

DR. OSTROFF: No. That's what we thought, too, but it has up to a two-week incubation period. So she just had the misfortune of breaking her hip and getting West Nile at the same time.

Maybe she was running from the mosquito. I don't know. But she's the only severe case so far.

PRESIDING OFFICER LaFORCE: But those serologic studies were acute cases, though. Those are still IGM.

DR. OSTROFF: Yes.

PRESIDING OFFICER LaFORCE: I mean, in terms of repeat infection, like the Dengue model, this doesn't sound like --

DR. OSTROFF: One of the problems that we have is that we have followed up most of the human cases from 1999 to look at long-term sequelae

of the infection and also to look at what their immune response is over time.

One of the problems that we have is that at least 50 percent of them appear to have persistent IGM at least 6 months out from their infection. And that's made life very difficult for us this year in terms of looking at people that are having specimens submitted to us because, even if we see IGM, we can't guarantee that it represents an acute infection because it may be left over from the year before. So that's complicated matters quite a bit.

The other thing is that in the area of Queens, where the outbreak was centered last year, to say that this was a multi-ethnic neighborhood is an understatement.

When we did the serosurveys, you know, you'd go to one house. And they were from the former Soviet Union and then two doors, they were from South America and several doors down, they were from somewhere else.

And so it took a lot of work because there are other flaviviruses around to make sure that the immunity that we were seeing was against West Nile and not against JE or whatever it was

where they came from.

We didn't see any evidence that there was protection from previous flavivirus infections certainly. And it didn't look like that that was a risk factor either. But the total number of seropositives that we have isn't huge.

PRESIDING OFFICER LaFORCE: Yes?

DR. BERG: Steve, you mentioned they were follow-up for those who have almost -- there was a report in the New York Times about one woman who still can't walk, --

DR. OSTROFF: Yes.

DR. BERG: -- another who took months to recover. Is there anything more

DR. OSTROFF: Well, yes, about 20 percent of them really didn't do well after the infection. But you've got realize these are really -- I mean, almost 50 percent of last year's cases were over the age of 70. So these aren't the healthiest people to begin with, even though many of these were pretty healthy individuals engaged in outdoor activities, et cetera. But it's clear it's not as benign as one would anticipate.

Actually, this year the 43-year-old in New Jersey, it's not generally known, but I won't

say anything more than he's involved in law enforcement and is not doing as well as one would anticipate at the age of 43 after this infection and hasn't been able to go back to work yet. He is close to a month out now.

PRESIDING OFFICER LaFORCE: Stay tuned.

DR. ALEXANDER: The saga continues.

PRESIDING OFFICER LaFORCE: I mean, this saga, we'll see where this takes us. It will teach us an awful lot.

Listen, Ben, have you got some closing remarks?

CLOSING REMARKS/ADJOURN

COL DINIEGA: Yes. Number one is the room will be secure overnight, but don't leave anything valuable. You can leave your papers in a nice stack. Nobody will come in and throw it away. Don't forget Dr. LaForce's get-together. We start at 0745.

PRESIDING OFFICER LaFORCE: Yes, 7:45, a little later tomorrow morning.

COL DINIEGA: And we have those powerful talks and a briefing. And then we have the discussion on the questions.

PRESIDING OFFICER LaFORCE: Thank you

all.

(Whereupon, the foregoing matter was concluded at 5:09 p.m.)